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             UNITED STATES DISTRICT COURT
            FOR THE NORTHERN DISTRICT OF OHIO
2
                  EASTERN DIVISION
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    IN RE: NATIONAL
                             MDL No. 2804
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   PRESCRIPTION OPIATE
    LITIGATION
                              Case No.
6
                              1:17-MD-2804
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    THIS DOCUMENT RELATES TO Hon. Dan A. Polster
    ALL CASES
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10
         HIGHLY CONFIDENTIAL - SUBJECT TO
11
         FURTHER CONFIDENTIALITY REVIEW
12
13
              VIDEOTAPED DEPOSITION OF
14
             CURTIS WRIGHT, IV, M.D., M.P.H.
15
16
             Wednesday, December 19th, 2018
17
                  9:01 a.m.
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19
        Held At:
20
             Grappone Conference Center
21
             70 Constitution Avenue
22
             Concord, New Hampshire
23
24
    REPORTED BY:
25
    Maureen O'Connor Pollard, RMR, CLR, CSR
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18 19	3245	20	Purdue-Wright-33 Document titled Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System, Bates 8841350087 252
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20 21	7032	21	Purdue-Wright-34 5/5/03 e-mail with attached RADARS System Report, Bates PPL PC013000094750 through 94788
22	OxyContin, Bates	22	PPLPC013000094750 through 94788
23	Purdue-Wright-15 Project Team Contact	23	
24	Report, Bates SHC-000008168 148	24	Purdue-Wright-35 11/16/99 e-mail with attachment. Bates PPLPC013000014822 through 14828
25		25	14828254
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1	_	1	Page 9
1 2	_	1 2	Page 9
	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689 155		Page 9
2	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689 155	2 3 4	Page 9  Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPI PC013000064640 through
2 3	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689 155	2	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689 155	2 3 4 5	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8 9	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
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2 3 4 5 6 7 8 9 10 11 12	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8 9	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12 13	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12 13 14	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12 13 14	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Purdue-Wright-16 OxyContin package insert, Bates PKY 183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Purdue-Wright-16 OxyContin package insert, Bates PKY183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Purdue-Wright-16 OxyContin package insert, Bates PKY183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Purdue-Wright-16 OxyContin package insert, Bates PKY183226682 through 6689	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Purdue-Wright-36 2/14/01 e-mail, with attached OxyContin FDA Negotiations Issues Document, Bates PPLPC013000064640 through 64643
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	Page 10		Page 12
1	Durdue Whight 45 1/15/19 demosition	1	PROCEEDINGS
2	Purdue-Wright-45 1/15/18 deposition transcript of Curtis	2	
3	Wright MD, Bates PKY 183389474 through 512 297	3	THE VIDEOGRAPHER: We are now on the
4	Purdue-Wright-46 Excernt of a 3725/04	4	record. My name is David Kim, I'm a
5	deposition transcript of Dr. Robert Reder, Bates PKY183344430 through 432 297	5	videographer for Golkow Litigation Services.
6		6	Today's date is December 19th, 2018,
7	Purdue-Wright-47 E-mail chain, Bates PPL-PC013000032858 through	7	and the time is 9:01 a.m.
8	800 307	8	This video deposition is being held in
9	Purdue-Wright-48 E-mail chain, Bates PPLPC013000040607 through	9	Concord, New Hampshire in the matter of National
10	609308	10	Prescription Opiate Litigation, MDL 2804, for
11	Purdue-Wright-49 Document titled	11	the U.S. District Court for the Northern
	Purdue-Wright-49 Document titled E513_00078820 with attached e-mail chain,	12	District of Ohio, Eastern Division.
12	Bates 8855884259 through 261	13	The deponent is Curtis Wright.
13	Purdue-Wright-50 Document titled	14	Counsel will be noted on the
14	Purdue-Wright-50 Document titled E513 00078832 with	15	stenographic record.
15	attached e-mail chain, Bates 8855931438 through	16	The court reporter is Maureen Pollard,
16	7440	17	and will now swear in the witness.
17	Purdue-Wright-51 Document titled E513_00019621 with	18	
18	E513_00019621 with attached e-mail chain. Bates 8855318499, 8500	19	CURTIS WRIGHT, IV, M.D., M.P.H.,
19	and 8003 311	20	having been duly sworn, was examined and
20	Purdue-Wright-52 3/25/97 letter, Bates PKY180423619 through 621 313	21	testified as follows:
21	Purdue-Wright-53 E-mail chain, Bates	22	MR. SNAPP: May I make a statement on
22		23	the record about the confidentiality protective
23	Purdue-Wright-54 Document titled E513_00082129 with	24	order?
24 25	attached e-mail chain, Bates 8856491648 318	25	MS. SINGER: Of course.
25	<b>Dates</b> 0050471040		MS. SHAGER. Of course.
	Page 11		Page 13
1	-	1	Page 13 MR. SNAPP: Thank you.
	Purdue-Wright-55 Excerpt of 8/28/15	1 2	_
1 2	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of		MR. SNAPP: Thank you.
2	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of Richard Sackler, MD,	2	MR. SNAPP: Thank you.  I just want to confirm that everyone
	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of Richard Sackler, MD, Bates PPLPC019001253034,	2	MR. SNAPP: Thank you.  I just want to confirm that everyone on the phone and in person agrees to be bound by
2	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of Richard Sackler, MD,	2 3 4	MR. SNAPP: Thank you.  I just want to confirm that everyone on the phone and in person agrees to be bound by the confidentiality protective order in the MDL
2	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of Richard Sackler, MD, Bates PPLPC019001253034,	2 3 4 5	MR. SNAPP: Thank you.  I just want to confirm that everyone on the phone and in person agrees to be bound by the confidentiality protective order in the MDL or the applicable state cases. If that is not
3 4	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of Richard Sackler, MD, Bates PPLPC019001253034,	2 3 4 5 6	MR. SNAPP: Thank you.  I just want to confirm that everyone on the phone and in person agrees to be bound by the confidentiality protective order in the MDL or the applicable state cases. If that is not the case, please speak up now.
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2 3 4 5 6 7 8 9	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of Richard Sackler, MD, Bates PPLPC019001253034,	2 3 4 5 6 7 8 9	MR. SNAPP: Thank you.  I just want to confirm that everyone on the phone and in person agrees to be bound by the confidentiality protective order in the MDL or the applicable state cases. If that is not the case, please speak up now.  Hearing nothing, please proceed.  Thank you.  EXAMINATION BY MS. SINGER:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Purdue-Wright-55 Excerpt of 8/28/15 deposition transcript of Richard Sackler, MD, Bates PPLPC019001253034,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. SNAPP: Thank you.  I just want to confirm that everyone on the phone and in person agrees to be bound by the confidentiality protective order in the MDL or the applicable state cases. If that is not the case, please speak up now.  Hearing nothing, please proceed.  Thank you.  EXAMINATION  BY MS. SINGER:  Q. All right. Good morning, Dr. Wright.  My name is Linda Singer, I'm an attorney for plaintiffs in the litigation.  Let me start by reminding you that you've been sworn in. You're here pursuant to a deposition notice, is that correct?  A. Yes, ma'am.  Q. I'm going to show you what we've marked we'll work out the kinks.  I'm going to show you what we're going to mark as Exhibit 1.  (Whereupon, Purdue-Wright-1 was marked for identification.)
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		-	archer confractionality Review
	Page 14		Page 16
1	do you recognize that notice?	1	A. Yes, ma'am.
2	A. I think so. It looks like the one I	2	Q. Okay. All right. So you indicated
3	received by e-mail.	3	I'm sorry.
4	Q. Okay. And have you prepared for your	4	Is there any reason that you can't
5	testimony today with anybody?	5	testify truthfully or accurately today?
6	A. Yes.	6	A. I know of no reason.
7	Q. And with whom did you prepare?	7	Q. Okay. And you said you've been
8	A. With my attorneys, and with two	8	deposed before, correct?
9	attorneys who I think represent Purdue.	9	A. Yes, ma'am.
10	Q. And is that your attorney seated next	10	Q. How many times, if you recall?
11	to you?	11	A. I don't really remember. I don't
12	A. Yes.	12	because I'm not sure exactly what the difference
13	Q. Okay. And do you recall who from	13	is between deposition and other legal
14	Purdue you prepared with?	14	interviews.
15	A. Erik and Marina.	15	Q. Okay.
16	Q. And about how much time did you spend	16	A. Two or three.
17	preparing for today's testimony?	17	Q. Okay. And how long has it been since
18	A. Several hours on four days.	18	you have testified in a deposition?
19	Q. Okay. And you counted on your	19	A. Many years. I don't know how many.
20	fingers, is that because it's less than ten or	20	Q. Okay. Have you testified in any
21	more than ten hours?	21	depositions in the last two years?
22	A. Just to try to be right.	22	A. No, ma'am.
23	Q. No, I appreciate that.	23	Q. What about at trial, have you ever
24	So do you recall roughly? You said a	24	testified at trial?
25	few hours?	25	A. Yes.
	Page 15		Page 17
1	MR. SNAPP: Several, he said.	1	Q. And tell us about the context in which
2	A. About 10 to 12 hours total.	2	you testified at trial. What was the case?
3	BY MS. SINGER:	3	A. That was a case involving disulfiram
4	Q. Okay. Did you review any documents in	4	toxicity many years ago.
5	preparing to be here today?	5	Q. Okay. And have you ever testified at
6	A. They presented me with a number of	6	trial in any case relating to opioids?
7	documents.	7	A. I don't remember any.
8	Q. Okay. And "they" being your counsel	8	Q. Okay. Or in connection with your work
9	or Purdue's counsel?	9	at Purdue Pharma?
10	A. Both, I think.	10	A. I don't think so, ma'am.
11	Q. Do you recall roughly how many	11	Q. And the depositions that you were a
12	documents you received?	12	witness in, did those relate to opioids, or to
13	A 37 A 1 .	13	other matters?
	A. No. A lot.	1	
14	Q. Okay. And one of the things I'll tell	14	A. They related to opioids.
14 15		14 15	<ul><li>A. They related to opioids.</li><li>Q. And can you recall the details of any</li></ul>
15 16	Q. Okay. And one of the things I'll tell	15 16	Q. And can you recall the details of any of those cases?
15 16 17	Q. Okay. And one of the things I'll tell you I know you've been deposed before, is that correct?  A. Yes, ma'am.	15 16 17	<ul><li>Q. And can you recall the details of any of those cases?</li><li>A. Only vaguely. One had something to do</li></ul>
15 16 17 18	<ul> <li>Q. Okay. And one of the things I'll tell you I know you've been deposed before, is that correct?</li> <li>A. Yes, ma'am.</li> <li>Q. Okay. So one thing I note that will</li> </ul>	15 16 17 18	<ul><li>Q. And can you recall the details of any of those cases?</li><li>A. Only vaguely. One had something to do with an insurance company and Purdue and their</li></ul>
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15 16 17 18 19 20 21 22 23	Q. Okay. And one of the things I'll tell you I know you've been deposed before, is that correct?  A. Yes, ma'am. Q. Okay. So one thing I note that will be important is, first of all, if you don't understand a question, please let me know, I am happy to rephrase it or repeat it.  And second is please, other than just this moment, when you're answering please	15 16 17 18 19 20 21 22 23	Q. And can you recall the details of any of those cases?  A. Only vaguely. One had something to do with an insurance company and Purdue and their insurance, I think. And I never really knew what the others were about.  Q. Okay. Do you recall if any of them were personal injury cases?  A. I don't think so.
15 16 17 18 19 20 21 22	Q. Okay. And one of the things I'll tell you I know you've been deposed before, is that correct?  A. Yes, ma'am.  Q. Okay. So one thing I note that will be important is, first of all, if you don't understand a question, please let me know, I am happy to rephrase it or repeat it.  And second is please, other than just	15 16 17 18 19 20 21 22	Q. And can you recall the details of any of those cases?  A. Only vaguely. One had something to do with an insurance company and Purdue and their insurance, I think. And I never really knew what the others were about.  Q. Okay. Do you recall if any of them were personal injury cases?

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Page 18

- medical training and background before joining 2 the FDA?
  - A. Yes, ma'am. I got my bachelors from Haverford College. Worked at a chemist at the
- National Institutes of Mental Health. Went to 6 night school, went to George Washington
- 7 University, did a -- got my MD degree. Went --
- 8 I did a general rotating surgical internship at
- 9 Naval Hospital Portsmouth, I had joined the
- 10 Navy. Served in the Navy for ten years -- eight
- 11 to ten years as a general medical officer. Went
- 12 to Johns Hopkins University, did a masters in 13 public health and an occupational medicine
- 14 residency. Then did a postdoctoral fellowship
  - in behavioral pharmacology of opioids. Then sat
- 16 for and took the boards in clinical 17 pharmacology. And I think that's it.
  - Q. Do you have any specialized training relating to addiction or addition medicine?
- 20 A. Yes. I was at one point an American 21 Society of Addiction Medicine certified 22 practitioner. And during my time in the Navy I 23 served for two or three years as the medical 24 officer for the tri-service alcoholism recovery

facility that handled alcoholism and drug

- Page 19
- 1 dependence.

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- Q. Okay. And any medical school training relating to addiction or fellowship or anything like that?
- A. Just the NIDA fellowship at Behavioral Pharmacology Research Unit.
- Q. And when did you join the Food and Drug Administration, or FDA?
  - A. I think it was 1989.
- Q. And why did you move to the FDA? Makes you smile?
- A. Well, my wife said that I either needed to get a paying job and stop going to school or we'd be moving into the park. I had three job opportunities at the time, and I applied, and I chose the FDA.
- Q. And why, other than the paycheck and vour wife?
- A. It was more attractive than the other two. It looked more interesting.
- Q. And what were your responsibilities in your first position at the FDA?
- A. I started as a junior medical officer reviewing investigational new drug applications and -- investigational new drug applications and

new drug applications.

- Q. And how long did you do that for?
- A. I'm not sure. At some point in there I was promoted to senior medical officer. I don't quite remember when. And I was also made head of the drug abuse staff in our review division.
  - Q. And how long were you at the FDA?
  - A. About eight to nine years.
  - Q. And what were generally your responsibilities over the course of your tenure?
- A. Review of investigational new drug applications, applications to study new drugs. Peer review of reviews that had been done by other medical officers. Consultative services to other FDA departments related to drug abuse issues. On several occasion I was acting division director.
  - Q. For which division?
- A. This was the -- had different names at different times. It started as the pilot drug evaluation staff, it was then HFD-170 of the pilot drug evaluation division, then its name changed, and I can't remember what they changed it to. It may have changed again, but it was

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all the same group of people.

- Q. Okay. And your role in that division covered the same responsibilities related to reviewing and assessing new drug applications?
  - A. Yes, ma'am.
- Q. And while you were at the FDA prior to your involvement in OxyContin, were you involved in the review or approval of any other opioid drugs?
  - A. Yes, ma'am.
- Q. Which drugs?
- A. I can tell you the ones I remember. I'd have to look at a list to tell it. But I was involved with pretty much every opioid that came through the division, was involved with, and some NSAIDs. I was involved with Duragesic. I was involved with -- now, the ones I remember
- 17 18 were just a mixed bag of opioid products, some
- 19 military morphine, nasal morphine came in; 20 several controlled-release opioids, I'd have to
- 21 look up to remember which ones; one or two
- 22 NSAIDs; some dosage form amendments. Just a 23 large collection of opioid drugs.
  - Q. Do you remember roughly how many opioids you had reviewed prior to OxyContin's

	Page 22	Ι	Page 24
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1	approval?	1	So were you not aware, or had it not
2	A. I would have to guess. I don't know.	2	become?
3	Q. Okay. Count them on two hands, or do	3	MR. PETRILLO: Objection to form.
4	you need more than that?	4	A. I was occupied full-time with my new
5	A. If you count investigational new drug	5	job, and I didn't I neither knew nor
6	applications, it would have been five or six, I	6	particularly cared.
7	think.	7	BY MS. SINGER:
8	Q. And when did you leave the FDA, what	8	Q. And how long were you at Adolor?
9	year?	9	A. A year to a year and a half.
10	A. I think it was 1997.	10	Q. And why did you leave?
11	Q. And why did you leave?	11	A. There was a mixture of reasons that I
12	A. I had been passed over for division	12	left Adolor. We had some discouraging
13	director for the third or fourth time, and it	13	information clinical trial results from our
14	was becoming clear to me that I would that I	14	lead compound. I was living apart from my wife
15	was it would be a long time before I was	15	and commuting to see her on weekends, which was
16	promoted or had any additional responsibilities,	16	very exhausting. We had great difficulty
17	and an extremely attractive offer came in from a	17	finding a home in the Adolor area. And my wife
18	pharmaceutical firm to be their chief medical	18	told me that she had been contacted by a
19	officer, and I accepted.	19	recruiter and I needed to think about other
20	Q. And do you know why you were passed	20	employment.
21	over for promotions at the FDA?	21	Q. So a certain through-line here.
22	A. Do you want an answer for now or from	22	And did you were you recreated to
23	then?	23	Purdue Pharma from Adolor?
24	Q. What you know now.	24	A. Yes, ma'am.
25	· · · · · · · · · · · · · · · · · · ·	25	
23	A. I wasn't ready. I did not have the	23	Q. How did that response how did that
	Page 22		~
	Page 23		Page 25
1	_	1	Page 25 opportunity come to you?
1 2	personnel management skills to be a division director.	1 2	opportunity come to you?
	personnel management skills to be a division director.		opportunity come to you?  A. A recruiter from a recruitment
2	personnel management skills to be a division director.  Q. And were you told anything by others	2	opportunity come to you?  A. A recruiter from a recruitment company, I believe, I don't know whether he had
2 3	personnel management skills to be a division director.  Q. And were you told anything by others at FDA at the time you were passed over for	2 3	opportunity come to you?  A. A recruiter from a recruitment company, I believe, I don't know whether he had a company or whether he was independent,
2 3 4	personnel management skills to be a division director.  Q. And were you told anything by others at FDA at the time you were passed over for these positions?	2 3 4	opportunity come to you?  A. A recruiter from a recruitment company, I believe, I don't know whether he had a company or whether he was independent, contacted my home, and my wife talked to him.
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	Page 26		Page 28
1	FDA about moving to Purdue?	1	projects to work on. I had a transdermal, a
2	A. No, ma'am.	2	sustained-release opioid, and an opioid
3		3	antagonist combination.
4	Q. All right. I'd like to show you Exhibit 2.	4	e
5			Q. So all three were opioid drugs, is
6	(Whereupon, Purdue-Wright-2 was marked	5 6	that correct?
	for identification.)		A. There's some dispute about how to call
7	MS. SINGER: This one we have enough	7	the transdermal, but yes.
8	copies of.	8	Q. Okay. And beyond your responsibility
9	BY MS. SINGER:	9	for those three drug products, were there any
10	Q. So, Dr. Wright, do you recognize	10	other tasks associated with your position?
11	Exhibit 2 titled "Curtis Wright IV, MD, MPH	11	A. Early on, no. Very quickly I began to
12	Curriculum Vitae"?	12	get questions from various people because of my
13	A. Yes, ma'am.	13	expertise in drug abuse and my previous
14	Q. Okay. I'm going to read the document	14	experience with the FDA.
15	number into the record. It's PPLPC013000116251.	15	Q. So it's fair to say that as with your
16	And you recognize this as your	16	position at the FDA, you also consulted with
17	curriculum vitae?	17	other people in the entity to give them your
18	A. This is one version of my curriculum	18	advice and opinions and experience?
19	vitae.	19	A. When they asked.
20	Q. Did you prepare this version of your	20	Q. Okay. And to whom did you report as
21	curriculum vitae?	21	executive director of medical research?
22	A. I believe so.	22	A. Robert Reder.
23	Q. Okay. I'd like to direct you to	23	Q. And did you have anyone who reported
24	Page 2, which is Bates number ending 52. And if	24	to you?
25	you look about two-thirds of the way down the	25	A. Yes.
	Page 27		Page 29
1	_	1	
1 2	Page 27 page, Executive Director, Medical Research, Purdue Pharma.	1 2	Q. Who was that?
	page, Executive Director, Medical Research, Purdue Pharma.		<ul><li>Q. Who was that?</li><li>A. It changed at various times because</li></ul>
2	page, Executive Director, Medical Research, Purdue Pharma. Do you see where I am?	2	<ul><li>Q. Who was that?</li><li>A. It changed at various times because people came in. There was Serge Carpow, Bob</li></ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	page, Executive Director, Medical Research, Purdue Pharma.  Do you see where I am?  A. Yes, ma'am. Q. And does that refresh your recollection as to when you joined Purdue? A. If I got it right, it was around 12/98. Q. Do you have any reason to believe you got that wrong? A. Only my general miserable problem with dates. Q. Fair enough. I share that fault. All right. Your first position at Purdue Pharma in 1998 or thereabouts was as executive director of medical research, is that correct? A. Yes, ma'am. Q. And what were your responsibilities as executive director for medical research? A. From what I remember, or what I wrote? Q. Why don't we start with what you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Who was that? A. It changed at various times because people came in. There was Serge Carpow, Bob Colucci, then Christopher Breder, then Dan Spyker, I'm moving forward in time, Douglas Kramer, Nab Dasgupta, and my eventually my secretary. Q. That's okay. Don't worry, I won't put you on the spot. So about how many people worked for you at any particular time? A. Including the people that worked under those people? Q. Yes. A. Nine to twelve. Q. And was Dr. Reader your supervisor for that entire period in that position? Did that change at all? A. I'm unsure. Q. You don't remember that it changed? A. Well, it did change. Dr. Reder was replaced as head of medical of that

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- A. Yes, different Kramer. And then I was moved out of medical research in terms of reporting to report to Dr. Haddox.
- Q. Okay. And did that change in your supervisor and the change in your position happen at roughly the same time, or were they separate events?
  - A. They were separate events.

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- Q. Okay. And was your next position once you moved as executive director of medical research and medical affairs, or is that kind of a continuation of the same job?
- 13 A. Well, it's really hard to say because I didn't move from one job to another and had a new job and new reports and new responsibilities. I carried one of the products all the way through until it was discontinued, carried another one about halfway and it was taken over by one of the new hires, and the third product ballooned into a multiple product product that I ended up being the medical officer for.
  - Q. Was that the naloxone project?
  - A. That was the Opioid X program.
  - Q. Okay. Which was the one -- of the

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- 1 A. I can't answer from a personnel perspective, because I did change who I reported 3 to at one point. But in terms of my work, it 4 gradually included more and more abuse and 5 diversion issues and tamper-resistant opioid 6 development issues, and I just carried the drugs 7 along with that.
  - Q. Okay. And in this growing role with respect to OxyContin and drug abuse and tamper-resistance, that's the work in which you reported to Dr. Haddox, is that correct?
  - A. OxyContin wouldn't be correct to say there, because the Opioid X programs were many potential products other than OxyContin. But, and I'm not -- I'm not sure that reporting to Dr. Haddox on the Opioid X program was right because there was a team leader and a team for the Opioid X, and that was Brianne Weingarten.
  - Q. Okay. And was Brianne Weingarten between you and Dr. Haddox, or a separate line of reporting?
  - A. I would characterize it as a separate line of reporting.
  - Q. Okay. And so Dr. Haddox was your supervisor with respect to the drug abuse and

Page 33

Page 31

- three products, the one that involved naloxone, 1 2 is that correct?
  - A. More than Naloxone, but yes.
  - Q. Okay. So you kept those three drugs even in this new position. Did you take on any additional responsibilities?
    - A. Yes, ma'am.
    - Q. And what were those?
  - A. I was the lead on the research unit that dealt with the -- I don't know how to describe it -- statistical understanding of OxyContin and other opioids' abuse and division.
  - Q. And did that division or department have a name?
    - A. I'm not sure what it was.
  - Q. Okay. And was this in your position in medical research and medical affairs, or was this a change that happened when you became executive director of risk assessment and health policy?
  - A. I would say it morphed into, from one into the other.
  - Q. Okay. So it was -- I don't want to put words into your mouth. It was an evolution rather than distinct jobs?

assessment work that you talked about earlier, is that accurate?

MR. PETRILLO: Objection.

A. I don't know how to answer that,

because I had a supervisor on paper, but

Dr. Haddox sometimes acted as my supervisor, 7 sometimes as my peer, and he was not supervisory

in the same way that Dr. Reder had been.

BY MS. SINGER:

- Q. And in what way was Dr. Haddox's supervision different?
- A. He left the management issues pertaining to the Opioid X program to Brianne.
- Q. Okay. And so during this period we're talking about with Opioid X and the drug abuse related responsibilities, was your title executive director of risk assessment and health
- A. I don't remember what my exact title was.
- Q. Okay. And are we talking about the time period from 2004 until you left Purdue?

MR. PETRILLO: Objection.

A. I'm not good with dates, and this process took place from the time that I came to

Page 34 Purdue until the time that I left Purdue. drugs, one we've put aside. Is there any other 2 2 BY MS. SINGER: drug whose development you were involved in at 3 3 O. Okay. And do you remember when you Purdue? 4 4 left Purdue? A. Excluding Opioid X? 5 5 Q. Yes. A. I believe it was 2005. 6 6 A. Well, the ones I remember are the HXA Q. Okay. We may come back to that one. 7 You mentioned the three products that program, the transdermal buprenorphine program, 8 you worked on over the course of your tenure at and Palladone. Everything else I remember was 9 9 involved with Opioid X. Purdue. Did any of those products precede to an 10 10 NDA submission to the FDA? Q. Okay. And the HXA product was what? 11 A. One of them did, I think. 11 A. That was an early conceptualization of 12 12 O. And NDA, just to make sure we're on a hydrocodone/naloxone combination. 13 13 the same page, is a new drug application? Q. What happened with that product? 14 14 A. A new drug application was filed for A. It was sucked up into Opioid X. 15 15 after I left the company, or must have been Q. When you joined Purdue its principle 16 16 products were opioids, is that correct? filed, I wasn't there, so I don't -- but it 17 17 MR. SNAPP: Object to the form. couldn't have -- I believe that one of the 18 18 A. The product that I knew about most was products came to the market. 19 Q. Okay. And which one was that? 19 MS Contin, but Purdue had other products, but I 20 20 A. Transdermal buprenorphine patch. was not involved with them. 21 21 Q. Okay. And would that have been Q. Is it fair to say that most of 22 Butrans, do you know? 22 Purdue's sales or revenue were related to

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A. I don't know the brand name, so I'm not -- I can't be positive, but I think that sounds right.

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BY MS. SINGER: Q. All right. I'd like to turn back to Exhibit 2, your CV. So looking at the middle

item, "Medical Research/Medical Affairs." Do vou see where I am in the middle of Bates number

opioids, if you know?

A. I don't know.

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A. Mm-hmm. 8 Q. Let me make sure I'm in the right 9

place. So can you read aloud the first paragraph under that item, "First executive director"?

MR. SNAPP: Object to the form.

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A. Starting with "Responsible"?

Q. "The first executive director of a newly created position."

A. "The first executive director of a newly created position to rapidly and proactively address and retard the urgent and growing situation of abuse of the corporation's largest selling prescription opioid analgesic."

Q. Does that accurately describe your duties in medical research and medical affairs?

A. It's a little grander than I actually was.

Q. In what way?

A. The actions that were -- my duties

Q. Okay. And what happened with the other two drugs? We can put Opioid X aside as I

know that is a longer story, but what about the second drug?

MR. SNAPP: Object to the form.

A. The other drug was called Palladone, and that development program was terminated. BY MS. SINGER:

Q. And why was it terminated?

A. It was terminated as a management decision, and I don't know exactly why. I do know that there were some technical problems with the formulation that were discovered very late in development.

Q. And do you recall what those technical problems were?

A. I can't say that they were the technical problems that caused the discontinuation, but it was vulnerable to alcohol, and if someone had been drinking alcohol before taking their pill the controlled-release properties could be distorted.

Q. Okay. And when you joined Purdue -and I'm sorry, so we've talked about the three

Page 38 1 dealt mostly with the scientific and medical 1 MR. SNAPP: Object to the form. 2 2 side of addressing abuse and diversion. A. I don't know how to answer that, 3 3 Dr. Haddox, Dr. Schnoll, another person whose because one of the products was a once a day 4 4 product using a different opioid. But I was not name I've forgotten, dealt with the medical 5 5 practice side. involved with, except as part of the Opioid X 6 6 Q. And by "medical practice," you mean program, with any modifications of OxyContin. 7 7 the practice of prescribers of the product, is BY MS. SINGER: 8 8 that correct? Q. Okay. All right. Returning to 9 9 A. Yes, ma'am. Exhibit 2, your CV, the third paragraph under 10 10 Q. Okay. And is it accurate to say that that same section on medical research and 11 you were the first executive director, and that 11 medical affairs, the last sentence, "This role 12 12 it was a newly created position? included providing medical affairs" -- do you 13 13 A. I think so. see where I'm reading, Dr. Wright? 14 14 Q. And in scaling this back to something, A. Mm-hmm. 15 15 the not so grand and more accurate, did you have Q. Can you read that sentence? 16 any responsibility for managing how Purdue's 16 A. "This role included providing Medical 17 17 opioids were marketed? Affairs direction and support in the development 18 18 A. No, ma'am. of non-branded education and focus group topics 19 Q. Did you have any responsibility or 19 and concepts regarding reduced abuse liability 20 authority with respect to where Purdue's opioids opioids." 20 21 were sold? 21 Q. And can you -- does that accurately 22 22 reflect one of your responsibilities? A. No. ma'am. 23 23 A. I think so. I provided direction with Q. Or how sales representatives were 24 compensated? 24 respect to medical affairs, but I had no power. 25 25 Q. You don't what? A. No, ma'am. Page 39 Page 41 A. I didn't have any authority. 1 Q. And you were not involved, I think as 1 2 2 you just said, in how prescribers were educated Q. Tell me what you mean by that. 3 3 on using Purdue's opioids, is that correct? A. And I'm not sure medical affairs is 4 A. I don't know if I was ever asked, and 4 the right word. I provided extensive opinion 5 if I was asked I would have given my opinion, when asked about how to address abuse and 6 but I had no authority over the marketing of diversion issues. I was asked on several 7 7 Purdue's products. occasions how to deal with issues pertaining to 8 8 bad prescribers or bad pharmacies, and I Q. And returning to your product 9 9 development work, did any of the products you provided the best answers I could. 10 worked on have any relationship to addressing 10 Q. And who were you asked by? 11 the 12-hour duration, or something called end of 11 A. I don't remember. There were multiple 12 12 dose failure of OxyContin? inquiries that would come in over time, I'd be 13 13 doing my regular work and then someone would ask A. Not that I remember. 14 Q. And did any of them address something 14 something, and I would answer. 15 15 we'll talk about later, but I think that you Q. So -- and I may be reading something 16 16 into your comments, but there seems to be described as the pharmacokinetic curve of 17 17 something undertone that you offered opinions OxyContin? 18 18 but they weren't taken. Is that true, or MR. SNAPP: Object to the form. 19 19 unfair? A. I'm unclear what your real question 20 20 MR. SNAPP: Object to the form. is. 21 BY MS. SINGER: 21 A. I was a voice. There were many 22 22 voices. Some voices had more experience in Q. So did any of the new drugs you dealing with physicians, Dr. Haddox for example. 23 developed seek to address the pharmacokinetic 23

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curve or the -- metabolizing the processing of

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OxyContin?

My voice carried a lot of weight with respect to

formulations, pharmacology, new drug products.

Page 42 I don't think I carried as much weight with 1 Q. Remembering your facility for dates. 2 2 respect to marketing because I didn't have any Do you remember to whom you offered 3 3 experience in it. those views? 4 4 BY MS. SINGER: A. It might have been Sally Riddle. 5 5 Q. But you did offer opinions on Q. And do you remember what, if anything, 6 marketing and on prescribing practices, is that 6 happened as a result of your views? 7 7 A. I don't know. correct? 8 8 MR. SNAPP: Object to the form. Q. Okay. All right. And we were talking 9 9 A. I wouldn't characterize it that way. a minute ago about your voice with respect to 10 BY MS. SINGER: 10 marketing. Do you recall any opinions you 11 Q. How would you characterize it? 11 offered on Purdue's marketing? 12 12 A. When someone asked me a question with MR. SNAPP: Object to the form. 13 13 respect to abuse, diversion, addiction, I gave A. I don't recall. 14 14 them my best opinion. BY MS. SINGER: 15 15 Q. And so although your voice didn't Q. All right. So let's go back to your 16 carry as much weight with respect to 16 CV, if we may, and you were reading a sentence 17 17 prescribers, do you remember your opinion that regarding your role, your direction and support 18 18 you offered when asked on those issues? in the development of non-branded education. So 19 19 MR. SNAPP: Object to the form. what was that work in particular? 20 20 A. I only remember specifically being A. At one -- I remember that project 21 asked when there was a question about what would 21 because it was, I thought, a good one. At one 22 help detail people identify potential problem 22 point, as part of Purdue's remediation program, 23 23 prescribers, prescribers who were prescribing they developed, I think with an external party, 24 improperly or diverting, and we did some 24 a program for adolescents, children, schools and 25 25 analysis on that, and I remember giving an young adults, to deter experimentation with Page 43 Page 45 1 opinion about that. opioids, and it was probably the best program 2 2 BY MS. SINGER: I'd ever seen. 3 3 Q. And was that the Top 200 program? Q. And you described it as part of 4 A. I don't remember that name. Purdue's remediation efforts. 5 Q. Okay. And do you recall what opinion A. Well, that's what I would call it. 6 you gave? 6 Q. Okay. And explain what you mean by 7 7 A. Yeah. that. 8 8 Q. And what was it? A. When something happens you do what you 9 9 A. That there were markers that would can to try to remediate it, to correct it, to 10 identify a clinic where the detail person should 10 minimize the damage, to make it better. I mean, 11 11 after a hurricane you come in and try to both be concerned. repair the damage and to remediate it to prevent 12 12 Q. And what were those markers? 13 13 future damage. A. I can't remember all of them now. But 14 they were relatively straightforward; does it 14 Q. And what was the -- what was the 15 15 look like a medical office, is there a underlying problem that you were trying to 16 16 remediate? receptionist and files, do the patients in the 17 17 waiting area look like a representative group of MR. SNAPP: Object to the form. 18 18 medical patients, was there anything unusual A. The rising abuse and diversion and 19 19 about the prescriber, were they interested in addiction to all opioids. 20 products other than strictly opioids. The other 20 BY MS. SINGER: 21 21 Q. And do you remember what the time characteristics were things that you could look 22 22 frame was for this work? up online. 23 23 Q. And do you recall roughly when you A. It was when I was in my second --24 offered those suggestions or indicators? 24 well, I can't be sure, ma'am.

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A. I can't remember.

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Q. And then the second part of that

Page 46 sentence in addition to the non-branded multiple technologies that were under 2 2 education was "focus group topics and concepts consideration. 3 regarding reduced abuse liability opioids." 3 Q. And what was the purpose of these 4 Correct? 4 various technologies? 5 A. Yes, ma'am. 5 A. The primary mode of abuse of 6 Q. And what did that work involve? 6 controlled-release opioids is to crush the 7 A. That was the Opioid X program. There tablet and destroy its controlled-release 8 were -- and I didn't run any focus groups, I had properties, then to either snort it or put it in 9 input to the people who did. There were 9 a teaspoon and inject it. And those are very 10 10 problems perceived as possible with high risk activities, and we wondered and tried 11 tamper-resistant and combination opioid 11 to see if we could make it impossible to do 12 12 products. The most -- the one I remember is why that. 13 13 should I prescribe a drug that's got something Q. And is it true, actually, that the 14 14 in it that's not going to benefit my patient to primary mode of abuse of controlled-release 15 15 benefit a drug addict, and one of the questions opioids is taking them orally? 16 was, how did you talk about that? How do you 16 MR. SNAPP: Object to the form. 17 convey to a physician that abuse and diversion 17 A. I actually can't answer that question 18 18 are inherent in these drugs, all of them, and accurately. Our concern with crushing, 19 19 that that must be managed. That's part of their dissolving, injecting was that those were high 20 lethality events, they could kill people. 20 job. 21 21 BY MS. SINGER: Q. So, and when you talk about the 22 question that was raised about prescribing a 22 Q. Okay. I'm sorry, so there are -- is 23 23 product that has something designed for drug it fair to say there are multiple ways to abuse 24 addicts, I think you said, who was that question 24 opioids? 25 25 or concern coming from? A. There are multiple ways to abuse Page 47 Page 49 MR. SNAPP: Object to the form. 1 1 opioid drugs. 2 2 A. That question came up from multiple Q. And that includes taking more pills 3 parties. I mean, within my own team, the 3 than you're prescribed, or taking the pills more 4 formulators, there were a number of people of 4 frequently, is that correct? 5 multiple disciplines who said why should a 5 MR. SNAPP: Object to the form. 6 patient take something that's not going to 6 A. You can take too much. 7 benefit them directly? 7 BY MS. SINGER: 8 8 BY MS. SINGER: Q. And then -- sorry, go ahead. 9 9 A. No, you could take too much. Q. And what was the reason for including 10 the naltrexone? 10 Q. Okay. And then you're talking about 11 11 another way of abusing them, which is snorting MR. SNAPP: Object to the form. 12 A. I think -- naltrexone, help me out, I 12 or injecting them, correct? 13 13 don't understand your question. A. Yes. 14 BY MS. SINGER: 14 Q. Okay. And so link this back, please, 15 15 to the conversation about the other Q. Sure. 16 So you've been talking about this 16 technologies. You were, I think, starting to 17 agent that was being added to opioids. Is that 17 get there. 18 18 agent naltrexone? MR. SNAPP: Object to the form. 19 19 A. Naltrexone was one of the agents that MR. PETRILLO: Same. If you need 20 we considered for adding to opioids. The 20 clarification, you can ask. 21 Opioid X program was very broad and had multiple 21 A. What about the other technologies? 22 intellectual properties and ideas associated 22 BY MS. SINGER: 23 Q. So when I asked you the purpose of the 23 with it, and one of them was adding naloxone and

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one of them was adding naltrexone. And there

were multiple ways to do that, and there were

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technologies, you started to explain that

opioids can be abused by crushing or snorting.

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So what was the role of these technologies with 2 respect to crushing and snorting and injecting 3 opioids?

A. There were multiple goals, because some of the technologies could accomplish some things, some could accomplish other things. One branch of the technologies was intended to

8 essentially render the opioid inert if you 9

tampered with the pill. Another branch of the

10 technologies was to make it physically very 11 difficult to tamper with the pill. There was

12 another group of technologies that would make

13 tampering with the pill less lethal. And

14 everything in-between. We quickly discovered

15 when we were wrestling with this that

16 tamper-resistance or abuse of --

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17 tamper-resistance is the best word, was not an

18 absolute, it was not a yes, no, could, or

19 couldn't. There were grades. Some technologies

20 were likely and very likely to prevent snorting.

21 Some technologies prevented injecting. Some

22 technologies prevented injecting and rendered

23 the narcotic inert so that you couldn't get high

24 from it or get a narcotic effect. There was

25 even one technology that was essentially

a product's attractiveness for abuse and 2 diversion protects the patient, it protects the 3 doctor, it protects the product, it protects 4

society.

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So from my perspective when asked why should I -- you know, why is this essential for a product, I would say abuse and diversion is bad, it hurts people, and you need to address

Q. And I interrupted you inappropriately to ask if OxyContin was a strong opioid.

MR. SNAPP: Object to the form.

A. OxyContin is a Schedule II opioid. BY MS. SINGER:

Q. And is that a strong opioid? I think you used that term, too.

A. Pure mu agonist opioid is more technically correct.

Q. So when you said strong opioid before, what do you mean?

A. Pure mu agonist.

Q. Okay. Which is -- OxyContin is a pure mu agonist?

A. Practically speaking. I don't know if it activates any of the other receptors, but it

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uncrushable. And all of these technologies were potential ways to make abuse and diversion more difficult.

Q. And you started by saying that there was resistance even among your own team to the use of some of those technologies, is that correct?

A. Yes, ma'am.

Q. And can you explain that again?

A. Yes. One objection that some of my peers felt might come up is why should a patient who is not abusing the drug be exposed to a second drug that they don't need and don't want to prevent abuse or diversion.

Q. And what was your own view of that?

A. Abuse and diversion are inevitable with any class -- any strong opioid, any Schedule II opioid.

Q. Is OxyContin a Schedule II opioid, a strong opioid?

MR. PETRILLO: I don't think the witness was finished.

23 BY MS. SINGER:

Q. Finish and we'll come back to it.

A. Limiting abuse and diversion, limiting

is predominantly a mu agonist opioid. 2

Q. You mentioned that there was an outside group involved in the non-branded education that you did. Do you remember what group that was?

A. No, ma'am, I don't.

Q. Who else worked with you on the non-branded education, if you recall?

A. I'm not even sure who worked with me. I remember being asked to review it, and I reviewed it.

Q. Do you remember who asked you to review it?

A. No, ma'am.

Q. And the focus group topics and concepts regarding reduced abuse liability opioids, who worked with you on the focus group piece of that?

A. I'm not certain there were focus groups on that. But that would have been Brianne.

Q. Brianne Weingarten?

A. (Nodding in the affirmative).

Q. And was there something else you could have been referring to with the use of focus

Page 54 1 groups in your CV? disadvantages in trying to grapple with abuse 2 A. I don't remember now. 2 and diversion was the information systems that 3 3 Q. All right. So we're going to move initially existed measured things like DAWN 4 4 forward to your role as executive director of mentions or drug abuse warning system mentions 5 risk assessment and health policy at the top of or emergency room visits by pharmaceutical 6 6 vour CV. compound, hydrocodone, oxycodone, morphine, all 7 7 One of the responsibilities you list generic terms. So there was no information on 8 8 for that position is potential product dosage form specific events, and there was no 9 9 acquisitions. Was that part of your information on geographical distribution, or 10 10 responsibility? very limited. 11 A. Yes, ma'am. 11 The RADARS program was the first 12 12 attempt to try to find out which pharmaceutical Q. And did that include any role in a 13 13 project to inquire -- excuse me, a project to products were being abused and diverted, and 14 14 acquire technology from Grunenthal? where that was located, and when it was. 15 15 A. I remember Grunenthal. I'm not Q. So it is the RADARS program that 16 certain what -- I don't remember now what their 16 you're talking about within this bullet item 17 17 product was. here? 18 18 Q. Okay. Do you remember anybody from A. Yes, ma'am. 19 Grunenthal with whom you worked or interacted? 19 Q. And what was your involvement with 20 A. I met them. I think we even presented 20 RADARS? 21 Opioid X to them. But I don't remember anybody 21 A. We, along with Sid Schnoll and David 22 22 Haddox, we provided technical ideas about how from Grunenthal. 23 23 Q. Okay. And do you remember what you might do it. 24 happened with that presentation, or after that 24 Q. And apart from RADARS, you did have 25 25 other sources of information about abuse and presentation? Page 55 Page 57 MR. SNAPP: Object to the form. 1 1 adverse effects, is that correct? 2 2 A. I do not remember, ma'am. MR. SNAPP: Object to the form. 3 3 BY MS. SINGER: A. There were other sources of 4 Q. And then in the same section of your 4 information. 5 resume you talk about "systems to assess and BY MS. SINGER: 6 manage opioid drug abuse and diversion," which I Q. And those included what? 7 think is the second bullet point under the third A. Adverse event reports, direct contacts 8 paragraph. to the company, safety reporting, published 9 9 A. Yes, ma'am. literature. I'm not sure I got them all, but 10 Q. Okay. Does that accurately describe 10 there were a variety of ways. 11 11 Q. Okay. All right. Let's turn to one of your responsibilities in the position? 12 12 (Witness reviewing document.) Exhibit 3. 13 13 Dr. Wright, if you need a break at any A. Patient is a bit much. We didn't 14 actually do that much patient level work. 14 point, please just --15 15 Q. And by "we," do you mean your MR. PETRILLO: Is now a good time for 16 16 division? a break? 17 17 A. Yes, ma'am. MS. SINGER: Now is a fine time. 18 18 THE VIDEOGRAPHER: We are now going Q. Okay. And then the third bullet 19 there, "Overall program." Do you see what I'm 19 off the record, and the time is 10:08 a.m. 20 20 referring to? (Whereupon, a recess was taken.) 21 21 THE VIDEOGRAPHER: We are now going A. Mm-hmm. 22 22 back on the record, and the time is 10:16 a.m. Q. And do you know what that work BY MS. SINGER: 23 entailed? 23 24 A. That was our involvement with the 24 Q. All right. Dr. Wright, we're going to 25 whole RADARS program. And one of the early 25 show you Exhibit 3.

Page 58 1 (Whereupon, Purdue-Wright-3 was marked someone else in there, but I'm blanking on it at 2 2 for identification.) the moment. But I would be left as a department 3 3 BY MS. SINGER: -- a party of one. 4 4 Q. So Exhibit 3 is Q. Administer without a portfolio. ENDO-OPIOID\_MDL-3004266, and it's title 5 5 And the people who were let go, did 6 Confidential Executive Profile, Curtis Wright, 6 they have a common function within the 7 7 department, or what were their collective roles? 8 8 Dr. Wright, do you recognize this MR. SNAPP: Object to the form. 9 document? 9 A. Doug Kramer was a medical officer. 10 10 Nab Dasgupta was a bachelor who was working on A. I do not recognize this document. 11 Q. Were you aware of the firm of Heidrick 11 his Ph.D who was a researcher in drug abuse. My 12 12 secretary, who was our group's secretary. I & Struggles? 13 13 A. I am not aware of the firm of Heidrick don't know if the epidemiologist went then or 14 14 & Struggles. not, I think so. 15 15 Q. Do you remember being considered or BY MS. SINGER: 16 approached for a position at Endo 16 Q. And who was the epidemiologist? 17 Pharmaceuticals? I saw a bell visibly go off. 17 A. I've forgotten her name. 18 A. Yes, I remember. Q. Okay. And so was that the part of 19 Q. When -- I'm not going to ask you when. 19 your department that worked on new drugs, or the 20 20 What did that involve? part that worked on drug abuse? 21 21 A. To the best of my recollection, Robert A. Those were all people that worked on 22 Reder, after he left Purdue, went to Endo. When 22 drug abuse. 23 23 I was looking for a job I believe I interviewed Q. And were you given a reason for the 24 with Robert. 24 layoffs at the time? 25 25 Q. Understood. A. My understanding, which is just what I Page 59 Page 61 And you see a date here of April, remember, was that there were financial 1 2005. Does that seem to be about the right 2 2 reversals within the company. 3 3 timing? Q. All right. So looking at this 4 4 Exhibit 3, I want to direct you to Bates number A. Well, I hadn't actually left Purdue 4268, which I think is Page 3, with 1998 to 2002 yet, I think. As I remember it, the news of the 6 layoffs came during CPDD, sorry, a scientific 6 at the top. 7 7 meeting, and that's generally held in June. Do you see where that is? 8 Q. Okay. So that would have been June of A. Mm-hmm. 9 9 2005? Q. All right. And if you can look at the 10 10 first bullet point, the very last sentence A. I think so. 11 Q. And which layoffs are you referring 11 starting "Transfer to Medical Affairs." Let me 12 12 to? know when you've found that. 13 13 A. The layoffs that resulted in my A. Yes, ma'am. 14 leaving Purdue. 14 Q. Can you read that sentence out loud, 15 15 O. And what was the extent of that please? 16 16 layoff? A. "Transfer to Medical Affairs to work 17 17 A. I don't know how big it was across the on Risk Management, a function that had not 18 18 whole company, but it was a -- it wiped out my existed in the firm before that time and for 19 19 department. which an urgent business need had arisen." 20 20 Q. The entire department? Q. And is that an accurate statement of 21 A. No, my half of it. 21 your function and the circumstances? 22 22 Q. Your half was which half? A. At this point in time I'm not certain 23 A. The scientific -- essentially the 23 that it had not existed before. 24 scientific research group, Dr. Kramer, Nab 24 Q. Okay. 25 25 Dasgupta, my secretary. I think there was A. And I've since learned that risk

Page 62 Page 64 1 management has a specific meaning in both 1 you think prompted it? 2 2 business and in pharmaceuticals, and I'm not MR. SNAPP: Object to the form. 3 3 A. I may have had something to do with certain that that is precisely correct either. 4 4 Q. And what do you mean by that? it. 5 5 A. From my perspective now, what I did BY MS. SINGER: 6 6 mostly was try to develop within medical Q. In what way? 7 A. Well, Dr. Haddox believed, as I did, alternative products that would manage the risk 8 of abuse and diversion, and to provide that all opioid drugs are vulnerable for the 9 development of an abuse and diversion problem, scientific and statistical methods that could do 10 10 all of them, and that when they happen they the same. But there was a whole other part of 11 risk management that I wasn't doing. 11 happen fast, and you had to respond fast and you 12 12 had to do something about them. O. And was there someone else who was 13 13 doing that? And one of the things I do remember 14 14 A. Oh, yes, ma'am. early on was that Dr. Haddox said, Curt, how can 15 15 Q. And who was that? we convince them, how can we explain that when 16 16 A. Within medical, within the medical this happens it will happen fast, and we need to 17 17 group it would have been Dr. Haddox, do something? And so I provided him with 18 18 Dr. Schnoll, and all of the consultants that coaching on what might happen. 19 19 they had external to the company that were Q. And when you talk about "them" in that 20 20 sentence who needed to be convinced, who are you working on the product-specific reporting 21 referring to? systems. There would have been -- I don't even 21 22 22 A. The company as a whole. know all the other people that were involved, 23 23 but there were. Q. And when you say you gave him 24 Q. And do you remember who the external 24 coaching, what did that involve? 25 25 consultants were? A. I remember him asking me what could Page 63 Page 65 A. No. 1 happen, and I told him what could happen, 2 2 because I'd seen it happen. Q. Okay. And was there a person who held 3 3 your position before you? Q. And what could happen? 4 4 A. No, ma'am. MR. SNAPP: Object to the form. 5 5 Q. Okay. And do you know what the A. The short -- there's a long answer, 6 instigator or trigger was for creating your and the short answer that's probably better is a 7 position? triggering event occurs that the company has to 8 8 A. I don't know for sure at the level of analyze, interpret, and respond to in a 9 9 senior management. corrective way right away. 10 Q. So you don't know who the person was? 10 BY MS. SINGER: 11 11 A. I have a strong suspicion. Q. And when you say you had seen it 12 12 Q. And what is your suspicion? before --13 A. That Dr. David Haddox was instrumental 13 A. I was -- yes. 14 14 in setting up that group. Q. -- what had you seen before? 15 15 Q. And on what do you base that? A. What was the question? 16 A. Well, he suddenly became my boss. But 16 Q. What had you seen before? 17 17

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when I had started at Purdue there was nobody with the epidemiological research/scientific analysis functionality working in the medical department, and suddenly that group appeared, and it appeared as a result of Dr. Haddox and he became my boss. So that's what I base it on. I think he did it.

Q. And was there a triggering event or circumstance inside or outside the company that

A. When I was at the Food and Drug Administration I was head of the drug abuse group, so all of the various abuse, diversion, crises that occurred during eight or nine years came through my desk.

Q. And when you say you had to -- there would be a triggering event, you'd have to act fast, is that because the speed, the scale of what was going to happen, the lethality? I

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Page 66 Page 68 1 mean, what are you talking about with that? 1 A. Yes. 2 2 MR. SNAPP: Object to the form. Q. Which opioids? 3 3 A. When an event occurs, early on you A. Do you wish me to include those that 4 have the potential to stop it. When it's become occurred at FDA that were historical that I had 5 widespread it's too late, you then have to try to learn about as the part of my job, or those 6 6 that actually occurred when I was -- on my to do what you can. 7 7 BY MS. SINGER: watch? 8 8 Q. And did the event of the abuse and O. Let's do both. So let's start with 9 9 diversion of opioids become widespread? the ones you learned about that preceded you. 10 10 MR. PETRILLO: Object to form. A. Okay. During the -- I'm not sure of 11 A. I think it is evident that there is a 11 the time frame. There has always been an effort 12 12 widespread problem with abuse, diversion and to try to develop less abusable opioids. Some 13 13 of the less abusable opioids were the partial addiction to all opioid drugs that we're in the 14 14 middle of right now. agonist or mixed agonist/antagonist opioids, 15 15 BY MS. SINGER: these are things like Talwin. I'm blanking, 16 Q. And when you talk in this Exhibit 3 16 it's been too long. I used to know them by 17 17 about an urgent business need, what was that heart. 18 18 urgent business need? Those were developed and were put in 19 19 A. A responsible company has to do lower schedules of the drug abuse scheduling 20 20 categories because it was believed and sometimes something. 21 21 Q. To prevent that kind of harm? hoped that they would have less abuse potential. 22 22 Some of them developed widespread abuse problems A. Prevent it --23 23 MR. SNAPP: Object to the form. and had to be rescheduled. Some of them 24 A. A company, from my perspective, that's 24 developed local outbreaks of abuse that had to 25 behaving properly anticipates what might happen, be controlled. Some of them developed sentinel Page 67 Page 69 is ready to identify what does happen, is able 1 1 cases that were so horrific that the company had 2 to analyze when that does -- what the event is 2 to respond because the case was so tragic. 3 3 And so there was always pressure to to find what's truly happening, and then has 4 thought about what they might do to correct it. 4 schedule, up-schedule drugs, there were always BY MS. SINGER: 5 pressures to do something to try to intervene in 6 Q. And those are all hallmarks of a 6 abuse and diversion outbreaks. 7 7 Q. And that pressure came, in your responsible company, correct? 8 8 opinion and experience, from a desire to protect MR. SNAPP: Object to the form. 9 9 A. I believe they're part of business patients and public health, is that right? 10 responsibility. 10 A. Yes, ma'am. 11 11 BY MS. SINGER: Q. Okay. So that's the historical piece 12 Q. And when you talk about what you had 12 that you were talking about, is that right? 13 13 A. I blurred because -seen in your years at FDA with other incidents 14 or epidemics of drug abuse, what were those? 14 Q. Okay. 15 15 A. That is also the things that happened A. They were so mixed and varied, I can't 16 16 -- it's difficult to do on the spot. on my watch, some of the things that happened on 17 17 O. So you've -my watch. 18 18 Q. And those things would be known to a MR. PETRILLO: I'm sorry, were you 19 19 finished? responsible company that was making and 20 A. Can you rephrase the question? Maybe 20 marketing opioids, correct? 21 21 MR. SNAPP: Object to the form. I can answer it. 22 22 BY MS. SINGER: A. That's tricky, because during that 23 23 time, not now, it's been too long, but during Q. So turning to your point about the 24 incidence or abuse epidemics you had seen at 24 that time I was an expert on pharmaceutical

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FDA, did any of them relate to opioids?

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problems associated with abuse of opioids. I'm

Page 70 not sure that most pharmaceutical physicians 1 Q. Was that typical for an FDA official 2 would have the breadth of knowledge that I had 2 to co-author an abstract with pharmaceutical 3 3 executives? at that time. 4 4 BY MS. SINGER: MR. SNAPP: Object to the form. 5 5 A. It depends on the division. In some Q. That's all knowledge you brought with 6 you to Purdue when you joined in 1998, correct? divisions it was not quite typical, in other 7 MR. SNAPP: Object to the form. divisions it would not happen. 8 A. I brought what I could with me to 8 BY MS. SINGER: 9 9 Purdue in 1998. I was still subject to the Q. Okay. And do you remember how this 10 Ethics in Government Act and the confidentiality 10 abstract in particular arose? 11 requirements of the FDA, so there were things 11 A. I don't remember the abstract at all. 12 12 that I knew about that were not in the public Q. Okay. And moving down your list of 13 13 domain that I could not talk to people at Purdue publications under the "Presentations At 14 14 about. Symposia and Scientific Meetings," do you see 15 15 the publication "Abuse Liability and Drug BY MS. SINGER: 16 16 Scheduling"? Q. But could you talk to people at Purdue 17 17 about the history and experience of drug abuse A. Yes, ma'am. 18 18 and drug diversion with opioids? Q. And is that a publication you still 19 MR. SNAPP: Object to the form. 19 have? Would you have retained a copy of that? 20 20 A. I was perfectly free to do that. A. I don't think so. 21 21 BY MS. SINGER: Q. Okay. What about moving down that 22 22 page, "Beyond Compliance with FDA Regulations"? Q. All right. And did you do that? 23 23 A. I did do that. A. That looks like it occurred at Purdue. 24 Q. So let's go back to Exhibit 3. At 24 Q. Okav. 25 25 Bates number 73, so turn forward if you would, A. Everything that I did at Purdue I left Page 71 Page 73 it's the page that has "Spyker" at the top of 1 1 at Purdue. 2 it. And do you see about halfway down an item 2 Q. Okay. Now, once you left Purdue, you 3 -- a publication that starts "Reder R"? 3 did not go to Endo, is that correct? A. Mm-hmm. 4 4 A. I did not go to Endo. 5 5 Q. Where did you go? Q. What is that publication? 6 A. It looks like an abstract presented at A. After I left Purdue, I attempted to 7 support myself as an independent consultant, CPDD. 8 8 pharmaceutical consultant. I was unsuccessful Q. And that's an abstract that you wrote 9 9 in 1993, correct, or co-wrote? in this. I eventually was contacted by Dan Carr 10 A. I believe I was cited as one of the 10 who asked me to come work on one of his projects 11 11 authors. that later became Javelin Pharmaceuticals. 12 12 Q. Okay. Do you see yourself listed as Q. Is Dan Carr a professor in Boston? 13 one of the authors? 13 A. Dan Carr is a professor in Boston, and 14 A. Yes, I do, ma'am. 14 a well-recognized analgesic expert. 15 15 Q. Were you still at Purdue when Purdue Q. Okay. And who were the other two 16 16 pled guilty to a series of misdemeanors relating authors? 17 17 to its misbranding? A. Robert Reder and Bob Kaiko. 18 18 Q. And were they both at Purdue Pharma? MR. SNAPP: Object to the form. 19 19 A. At that time I believe they were. A. When did that occur, do you know? 20 Q. And is that typical to co-author 20 BY MS. SINGER: 21 publications from regulated entities? You were 21 Q. 2007. 22 at FDA at the time, they were at Purdue Pharma, 22 A. No, ma'am. 23 23 Q. And when you were at Purdue, did you yes? 24 MR. SNAPP: Object to the form. 24 interact directly with any member of the Sackler 25 25 BY MS. SINGER: family?

Page 74 1 A. Very rarely. I interacted with them unit, and I don't know all of the things that 2 2 socially on two or three occasions. I had a they worked on down there. 3 3 couple of conversations with Dr. Richard or BY MS. SINGER: 4 Dr. Kathy because they were wanting to ask me 4 Q. Was the drug discovery group Purdue 5 5 questions about some new thing they were Research Center, or did it have a different 6 6 interested in, and that's about it. 7 7 Q. And do you remember the specifics of A. I was only there twice, and I'm not 8 any of those conversations? 8 sure I know what the proper title of that place 9 9 A. I can't be certain. I think one of 10 them involved someone who was presenting a novel 10 Q. Okay. Did you receive any deferred 11 inhaled analgesic. The other one I don't 11 compensation when you left Purdue, any kind of 12 12 remember. severance or... 13 13 Q. Okay. And did you ever interact with A. To my recollection, I received a 14 them in particular on Opioid X? 14 severance package when I left Purdue. 15 15 A. Well, it depends on what you mean by Q. And are you being compensated for 16 "interact with them." We gave multiple 16 preparing or testifying today? 17 presentations on Opioid X, and I'm sure that 17 A. Not to my knowledge. 18 some of them the Sacklers were at because it was 18 Q. You should probably know. 19 the annual scientific meeting or they came, but 19 And do you know if Purdue is paying 20 20 for your counsel? I was just giving my presentation. 21 21 Q. And the annual scientific meeting was A. I hope Purdue is paying for my 22 22 what? counsel. 23 23 A. At one point during the year, and I Q. Fair enough. 24 don't remember when it was, we would present to 24 All right. Let's turn back to your 25 the Sacklers what had happened to the -- what time at the FDA. So I think you've already Page 75 testified, if not I'll ask you again, you worked 1 was -- what had happened, what was under 2

development, future directions that we might go. We just got an assignment, and we did our assignment and presented it.

Q. Okay. And that's what you refer to being the annual scientific meeting, it was a meeting between officials in the company and the Sackler family?

MR. SNAPP: Object to the form.

A. It was a pretty big show, because I think it was also to some of the other employees who weren't directly involved in the research, so it was usually held in a large venue. I don't know how frequently for sure, but I know about it because I inadvertently sat in the Sackler family section and quickly got shooed out.

18 BY MS. SINGER:

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Q. Were you aware -- or was Purdue, to your knowledge, involved in the development of any addiction treatment drugs during your tenure?

MR. SNAPP: Object to the form.

A. I truly don't know, because we had for a period a drug development -- a drug discovery Page 77

on the new drug application for OxyContin,

correct?

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A. That is correct.

Q. And had you been involved with oxycodone related products before, oxycodone products before?

A. I don't remember.

Q. And had you been involved in any controlled-release product approval?

A. Yes.

Q. And had you ever been involved in assessing or approving the controlled-release version of an existing drug?

A. Could you repeat the question?

Q. Yes.

Had you ever been involved in assessing or approving the controlled-release version of an existing drug?

A. Yes.

Q. Do you remember which one that was?

A. There were -- no. There were a bundle of opioid controlled-release forms that came piling in, and I was involved -- would have been involved with them, but I don't remember them

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one by one.

Q. Do you recall what you were looking for in deciding whether to approve OxyContin?

MR. SNAPP: Object to the form.

MR. PETRILLO: Objection.
Let me just direct you, Dr. Wright,
not to reveal any communications within FDA,
which I don't think you're permitted to do.

A. I can speak of my own, for myself personally. I cannot speak for the FDA. The FDA speaks for the FDA. When a -- there was a -- I won't say fad. But there was a period in which controlled-release technology made advances, and people brought in a variety of drugs wishing to have controlled-release dosing, and those were referred to as immediate-release to controlled-release switches.

The important features that were always looked at by me were what's the peak concentration at the proposed dosing interval, what's the trough concentration, are there any safety hazards associated with the product that are associated with its controlled-release features, and where it needed to be, where appropriate, what was the clinical efficacy

<sup>1</sup> A. When you -- yes, I can.

Q. Please go ahead.

A. When you take a drug you have -- we'll assume you haven't taken it before, there's a lag because you have to get into your stomach, and then the blood level in your blood will start to rise, it will reach a peak, and then it will start to fall, and then it will fall to subtherapeutic levels.

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Q. And why does the peak matter?

A. Generally the speak is associated with the peak effect and the peak toxicity.

Q. Okay. Meaning that's when you get the benefit of the drug?

MR. SNAPP: Object to the form.

A. And the bad things.

## BY MS. SINGER:

- Q. And then you talked about looking at the trough, correct? And why does the trough matter to you?
- A. The trough is when the effect can wear off, and the drug is no longer providing the benefits to the patient.
- Q. Okay. All right. So you mentioned before you're looking at the peak, you're

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outcomes and what were -- were there any

- unanticipated safety outcomes. That's what I
- 3 would look for.
  - BY MS. SINGER:
    - Q. And can you just explain briefly the difference between an immediate-release and a controlled-release drug?
      - A. Yes, I can.
      - Q. Could you?
    - A. An immediate-release drug, the absorption is determined by the drug theoretically dissolves immediately upon entry into the stomach, and then is absorbed at a rate that's determined by the transmission across the stomach into the bloodstream and passage through the liver and lungs.

For a controlled-release, the tablet has some intrinsic property, tablet, patch, lozenge, something you put in your mouth, there's all kinds of different ways, has some intrinsic property that slows the release and delivers the drug over time.

Q. Okay. And you talked a minute ago about looking at the peak concentration. Can you explain what that is?

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looking at the trough, I think you also said, correct me if I'm wrong, that you're looking at

efficacy. When you were looking at the

<sup>4</sup> efficacy, did you want to see that the

controlled-release had the same efficacy as the immediate-release?

MR. SNAPP: Object to the form.

A. Desirable, but not necessary.

## BY MS. SINGER:

Q. Okay. And did it matter from -- well, at the time OxyContin was assessed and approved, was there any discussion of what it would be scheduled as?

MR. SNAPP: Object to the form.

A. You're asking about discussions that took place within the Food and Drug Administration, and that is privileged, I believe.

However, oxycodone is a Schedule II opioid, and I cannot imagine it ever being anything but a Schedule II opioid.

BY MS. SINGER:

Q. Okay. Now, you were the medical officer who also reviewed the studies Purdue submitted with its application, correct?

Page 82 Page 84 1 A. No. 1 Purdue on various drafts. 2 2 Q. Did you review any of the studies? Q. And the original draft of the package 3 3 A. Yes, I reviewed all of them, but I was insert you said came from Purdue? 4 4 not the primary reviewer on some of the studies. A. Yes, although at that time it was 5 5 Q. And FDA doesn't conduct any of its own fairly common for us to provide companies with 6 6 studies in approving a drug, does it? an outline of what we were trying to move the 7 7 MR. SNAPP: Object to the form. controlled substances package inserts towards. 8 8 They were very heterogenous because they covered A. You're asking a question that extends 9 beyond my knowledge, because FDA does conduct a 30, 40 year span, and some of them were very 10 10 studies and it -- but it is not routine for good and some of them were very bad, and I was 11 pharmaceutical company applications for -- well, 11 directed by my division director. 12 12 FDA does conduct studies. The extent and MR. PETRILLO: Objection. 13 13 If you can testify without talking magnitude of studies that they conduct and when 14 they conduct them is beyond my knowledge because 14 about conversations or directions from within 15 15 it is so broad. the FDA, that would be preferable. 16 16 BY MS. SINGER: THE WITNESS: Yes, I'm sorry. 17 17 Q. Did FDA conduct any of its own studies MR. PETRILLO: If you want to testify 18 related to OxyContin? 18 to what you actually did, that's fine. 19 A. Prior to approval? 19 A. Okay. I had for some reasons a goal 20 Q. Yes. 20 of trying to get a good package insert for all 21 21 A. Not to my knowledge. the narcotics that were coming in for re-review 22 Q. Did it conduct any studies after its 22 or new review. 23 23 approval? BY MS. SINGER: 24 A. If they occurred after '97, I wouldn't 24 Q. And what's a good package insert? 25 25 A. One that has a reasonably -- has know. Page 83 Page 85 1 Q. Okay. And in assessing and approving reasonably uniform language, is comprehensible, 2 OxyContin, the new drug application for 2 is clear, and has easy to find sections in which 3 OxyContin, you relied on the studies that Purdue 3 you can find specific information that you need 4 submitted and the general literature, correct? to know as a doctor. 5 MR. SNAPP: Object to the form. 5 Q. Now, there is a separate division at 6 A. As a matter of policy we would have FDA that oversees some of the promotional 7 relied upon the studies that were conducted by activities related to prescription drugs, 8 8 the company, the reports of the division of correct, that didn't fall in your division? 9 9 scientific investigations on the conduct of A. No, there's the division of drug 10 those studies after they investigated them, our 10 advertising. 11 11 general knowledge, the results of other -- other Q. Okay. Also known as DDMAC, correct? 12 12 science that the agency held that would tell A. DDMAC. 13 them about the safety or efficacy of a potential 13 Q. And you weren't directly involved in 14 product, general knowledge of the reviewers, and 14 overseeing the promotion of OxyContin? 15 15 MR. SNAPP: Object to the form. I think that's about it. 16 16 Q. Okay. And as part of the approval A. I was not directly involved in 17 17 process you developed a package insert, correct? overseeing the promotion of OxyContin. 18 18 BY MS. SINGER: 19 19 Q. Okay. Correct --Q. Okay. And you seemed to hesitate. 20 A. The company developed a package 20 Was there a reason for that? 21 21 A. Yes. DDMAC often used us as a 22 22 Q. Okay. And you worked with Purdue on technical reference. various drafts of that package insert, is that 23 23 Q. And were you a technical reference in 24 correct? 24 any of the promotion relating to OxyContin? 25 25 A. Everyone involved would work with MR. SNAPP: Object to the form.

Page 86 1 A. I think you're asking about -- I think 2 I can't answer that properly. 3 BY MS. SINGER: 3 4 Q. Okay. So as a matter of policy and 5 5 practice, the FDA's marketing oversight is drug. 6 related to marketing or promotional pieces that 6 7 are distributed by a pharmaceutical company, is 8 pages? that correct? 9 9 MR. SNAPP: Object to the form. A. Many. 10 10 A. To my understanding, yes. 11 BY MS. SINGER: 11 12 12 Q. Okay. And the FDA does not have a 13 13 role in all of the different ways that a 20, 30. 14 14 prescription drug is promoted, correct? Q. Pages? 15 15 MR. SNAPP: Object to the form. 16 A. I truly don't know. I know that we 16 17 17 have -- that the FDA had a division of drug 18 advertising. I do not know the breadth or 18 correct? 19 19 extent of their responsibilities or powers. 20 20 BY MS. SINGER: 21 21 Q. Okay. And do you have a view as to 22 22 who is responsible -- a view as to whether it's 23 23 a drug company's responsibility to ensure that 24 its marketing is accurate and fair and balanced? 24 BY MS. SINGER: 25 25 A. My understanding of the regulations

a drug which should be reviewed by anybody who prescribes it, and is a source document that is used to assess the use, dosage, safety, and special precautions involved in prescribing a Q. And do you remember roughly how long

- the package insert was for OxyContin, how many
- Q. Can you count them on your fingers again, or do we have to get extra hands?
- A. It would depend on the typeface. But
  - A. (Nodding in the affirmative).
- Q. Okay. And the fact that there is -and the FDA approves the package insert,

MR. SNAPP: Object to the form.

- A. It's difficult because I don't know whether the FDA approves a package insert or does not object to a package insert, but the FDA certainly reviews a package insert.
- - Q. Okay. And the fact that the FDA has

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are that a drug company has a responsibility to meet the DDMAC guidelines in marketing their product.

Q. And that includes making sure that their advertising is fair and balanced and accurately conveys the risks and benefits of a product?

MR. SNAPP: Object to the form.

A. It's hard to be accurate in answering you because I didn't work in DDMAC, and I don't know the extent to which their -- I don't know their standards.

BY MS. SINGER:

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Q. Fair enough.

Looking at it from the perspective of the label, then, which is really where you were working, is that correct?

MR. SNAPP: Object to the form.

BY MS. SINGER:

Q. The FDA -- the fact that there is an FDA-approved label and package insert -- I'm sorry, let's step back.

What is a package insert?

A. A package insert is the full labeling information -- full prescribing information for reviewed or approved a package insert, whatever the right term is, the right verb, that doesn't prevent a company like Purdue from warning of additional risks that become known to it, is that correct?

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MR. SNAPP: Object to the form.

A. That's a tough problem, because I don't know if a company -- and it's come up. I don't know if a company can provide additional -- can change its package insert to provide additional warnings without notifying the agency and getting their lack of disapproval or approval, whatever it is. I don't know for sure.

## BY MS. SINGER:

Q. You don't know. Okay. We'll leave it there then.

There are other ways that a drug company discloses risks to prescribers and patients, correct, outside of the package insert?

MR. SNAPP: Object to the form.

A. You're asking questions about DDMAC practice that I -- that are beyond my expertise. BY MS. SINGER:

Page 90 1 Q. Okay. So turning away from DDMAC, is 1 Q. Okay. "A company" meaning a Purdue 2 2 it fair to say that a pharmaceutical company is document? 3 responsible for ensuring that the drugs they 3 A. (Nodding in the affirmative). 4 sell are safe and effective? 4 Q. Okay. And if you can take a look at 5 5 the content of the discussion, and just read it MR. SNAPP: Object to the form. 6 A. Again, that's tricky, because it's 6 to yourself for a moment. 7 7 safe and effective used as directed. And the (Witness reviewing document.) 8 8 goal of the whole FDA approval process is that Q. Do you recall the discussion that's 9 9 described in this project team contact report? the product reaches the market safe and 10 10 effective used as directed. A. No, I don't, ma'am. 11 11 Q. Okay. Do you recall talking to BY MS. SINGER: 12 12 Dr. Reder about osteoarthritis studies related Q. And that -- and is it fair to say that 13 13 there's an expectation that there's an alignment to OxyContin? 14 14 between the indication and the use? A. This document says that I did. I 15 15 MR. SNAPP: Object to the form. don't remember. 16 A. That is a -- no. That is a painful 16 Q. Okay. All right. Let's turn to --17 17 and sore point. The FDA is federal, and it (Whereupon, Purdue-Wright-5 was marked 18 18 regulates the pharmaceutical industry. The for identification.) 19 regulation of the practice of medicine devolves 19 BY MS. SINGER: 20 20 to the individual states. So it would not be Q. Exhibit 5 is PDD 9520512001. And it's 21 21 unusual for a medication to have off-label use titled -- it is the second exhibit from the 22 22 deposition of you, Dr. Wright, July 25th of and off-label indications that are not 23 23 referenced in the package insert, but which are 2003, the font is really difficult, but I'd like 24 used by physicians. 24 to direct you to Bates number 263. 25 25 BY MS. SINGER: All right. Do you see your name as an Page 91 Page 93 FDA attendee in the middle of this page? 1 Q. Off-label indicate -- actually we 2 A. Yes. 2 don't need to go down that rabbit hole. 3 3 MR. SNAPP: Do you think we could give And a drug company in its outreach in 4 marketing a product interacts with healthcare 4 the witness the time to just look through the 5 prescribers, healthcare providers about the use document to make sure he knows what it is? 6 of its drug, correct? 6 MS. SINGER: If he needs it, 7 7 MR. SNAPP: Object to the form. absolutely. 8 A. Yes, ma'am. 8 MR. SNAPP: Thank you very much. 9 9 BY MS. SINGER: (Witness reviewing document.) 10 Q. And when we get into the regulation of 10 BY MS. SINGER: 11 that we leave your area of expertise, correct? 11 Q. All right. Do you recognize this 12 12 A. (Nodding in the affirmative). document, Dr. Wright? 13 13 Q. Okay. Let's turn to the next exhibit, A. (Nodding in the negative). 14 which is 1484. 14 Q. Okay. Do you see --15 15 (Whereupon, Purdue-Wright-4 was marked A. I'm sorry, I have to respond verbally. 16 for identification.) 16 I don't remember it now. 17 17 MS. SINGER: I think we're back down Q. Okay. Thank you for policing yourself 18 18 to two of these. Exhibit 4 is PKY180764184. on that. 19 19 And it's titled Project Team Contact Report. Do you see yourself in the middle of 20 Bates number 263 as an FDA attendee at this 20 BY MS. SINGER: 21 Q. And, Dr. Wright, I see you're looking 21 meeting? 22 at it. Is it familiar to you, this form of 22 A. Yes, I do, ma'am. 23 23 document? Q. Okay. And do you know who Ms. Emmet 24 (Witness reviewing document.) 24 is? 25 A. No. This is a company document. 25 A. She would have been a consumer safety

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officer at the Food and Drug Administration.

- Q. Okay. And do you see, if you look at the first line on the paragraph, the bottom paragraph that starts "Ms. Emmet began the meeting with a strong recommendation that Purdue
- 6 Frederick participate in the Pilot Drug 7 Division's pilot management system for reviewing
- 8 drug development programs." 9

Do you see where I am?

A. Yes.

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- Q. What is the pilot drug division project management system?
- A. It was how we handled new drug applications or drug development programs with companies when we could.
- Q. Okay. And what was the pilot about it?
- A. When I was hired into the FDA, I was initially to go to the neuropharm division, but between the time that I applied and I showed up the drug class that I was working with had been transferred to something called the pilot drug evaluation staff, and that was a division that reported directly to the center director and was

led by Dr. John Harter that was specifically

- - A. You have read that correctly.
  - 2 Q. Okay. And so PF is Purdue Frederick. 3 And the IND is what you talked about earlier, 4 the drug approval process?
    - A. No, the IND is investigational new drug application which is the document that permits new drug studies to be started and done.
    - Q. Okay. So do you recall Purdue submitting minutes of its meeting with FDA, and you in particular?
    - A. They would have gone to Ms. Emmet or to the other consumer safety officer, and I may or may not have seen them. I don't remember any of them.
    - Q. Okay. And do you know whether it was the practice of Ms. Emmet or FDA to review these minutes?
      - A. It was my belief that they did.
    - Q. And then while we're in this document, let's turn the page to 265. Right in the middle of the page it says "Dr. Wright will send his FDA's high dose opioid policy to facilitate our generation of labeling with respect to the warning section."

Do you see where I am?

Page 95

- tasked with improving the agency's effect -- the Center for Drug's effectiveness in reviewing new drug applications.
  - Q. Okay. And when you talk about the center, just tell us which center it is.
    - A. Center for Drugs.
    - Q. Okay. Is that also known as CDER?
    - A. Yes, ma'am.
  - Q. And it says here -- so do you know if Purdue participated in the pilot drug division's project management system in its application for OxyContin?
    - A. I believe they did.
  - Q. Okay. And if you move down this paragraph, about four lines up it says "Each interaction between FDA and PF should be recorded and submitted to the IND (batching of records may be done on a regular basis). The timelines for each of FDA's projects is reviewed monthly at FDA, a meeting to which the PF project manager is also invited. PF is responsible for keeping minutes of all meetings. These will be official minutes unless FDA
- 24 disagrees." 25 Have I read that correctly?

- A. I see where you are.
- Q. Okay. And what is the FDA high dose opioid policy?
- A. I don't know it by that name. With, I think it was -- I cannot remember the product but I think it was Duragesic, it was the first time that a company submitted a request for a high dose opioid that would be too high to give to an opioid naive patient, someone who had not received opioids before, that if by accident it was prescribed or used for a patient that was not -- did not have opioid tolerance, that they could get sick or die. And I was, as a reviewer and as a doctor, very concerned about that. And I remember struggling with how to identify, flag, package, think about, label such products so that such accidents wouldn't happen.
- Q. Okay. And so that's what you think is expressed by the high dose policy?
  - A. I think so.
- Q. Okay. And do you know if there's an official document that reflects it?
  - A. I don't know.
  - Q. And then let's turn to Exhibit 5 -- 6.

Page 98 Page 100 1 (Whereupon, Purdue-Wright-6 was marked 1 wrong number. 2 2 for identification.) A. Okay. 3 3 Q. Okay. Is that Exhibit --BY MS. SINGER: 4 Q. And Exhibit 6 is PPLPC018000725809 4 A. 4. 5 5 Q. -- 4? Okay. titled "Criticisms and Allegations Potentially 6 Requiring Response in Connection with the Senate 6 All right. And I know you didn't 7 Finance Committee Inquiry." recall this document, but I just want to see if 8 8 Are you familiar with this document? any of the content here refreshes your 9 9 A. No, I am not, ma'am. recollection. It says three lines down, "Of 10 10 Q. Okay. So I just want to turn to Bates greater importance is the fact Dr. Wright said 11 number 809 -- that's wrong. 5857. And you see 11 that for certain individuals in the division and 12 the section -- I'll let you get there. You have 12 in the agency, the use (i.e., long-term) in 13 13 your own heading, "Purdue did not improperly osteoarthritis is unwarranted." 14 influence Dr. Curtis Wright." 14 Do you recall saying that to Purdue 15 15 Do you see that? Pharma? 16 A. Yes. 16 A. I don't recall it, but it is very 17 17 Q. And do you see halfway through the likely. 18 page in the paragraph beginning "Critics," three 18 Q. And what do you base that on? 19 19 lines from the bottom of that paragraph, "Purdue A. Our division -- as a matter of policy, 20 20 recorded all communications with Dr. Wright, our division was very sensitive to claims for 21 21 whether formal or informal, in internal contact therapeutic efficacy and osteoarthritis because 22 reports, and submitted summaries of such reports 22 we also handled the non-steroidal 23 23 to the FDA on a regular basis." anti-inflammatory drugs, and that is a huge 24 Do you see that? 24 issue with that class of drugs, and I can 25 25 A. Yes, I do. readily believe that I made explicit statements Page 99 Page 101 Q. Okay. And does that seem consistent 1 1 to Purdue that this is not a drug for unselected 2 2 with what we were just talking about with the OA. 3 3 regulatory contact reports? O. OA is? 4 MR. PETRILLO: Objection to form. 4 A. Osteoarthritis. 5 A. I only know my side of communications Q. It goes on to say "The way the 6 with Purdue and with other companies during that protocols are written, it looks as if Purdue 7 period of time, and we simply never met with the Frederick is attempting to obtain labeling 8 company alone and always had the consumer safety 8 claims for pain from osteoarthritis. This will 9 9 officer with us. So the consumer safety officer be strongly resisted." 10 10 should have had personal access to either the That strikes you as true as well? 11 communication as it was occurring and her notes, 11 MR. PETRILLO: Objection. 12 12 or whatever notes the company may have written. A. It is very typical of what we would 13 BY MS. SINGER: 13 have said. Q. Okay. And that would have been 14 14 BY MS. SINGER: 15 15 Ms. Emmet in this case? Q. Now, osteoarthritis, if you know, is a 16 MR. SNAPP: Object to the form. 16 fairly prevalent condition, is it not? 17 17 A. Consumer safety officers sometimes MR. SNAPP: Object to the form. 18 covered for each other and changed in the course 18 A. As with most medical conditions, it 19 19 depends on what you mean. Osteoarthritis can be of a project, but it would have been whoever the 20 20 duty consumer safety officer was. my fingers are a little sore in the morning, and 21 BY MS. SINGER: 21 osteoarthritis could be I can't walk, and I've 22 Q. Okay. All right. I want to turn back 22 been out of it too long to know what the current 23 23 to what was Exhibit 4, which is the project team numbers are for severity by diagnosis.

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contact report, which is PKY180764184. It's the

short one, Dr. Wright. I may have given the

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Q. Or prevalence, just what percentage of

the population has it?

	Page 102		Page 104
1	A. Osteoarthritis is common. Severe	1	A. The applicant has a much higher burden
2	osteoarthritis is less common.	2	of proof.
3	Q. And then if you keep going down this	3	Q. Okay. And that would include a study,
4	page, it says single "and that Purdue	4	correct?
5	Frederick recognizes single-entity opioid use is	5	A. Well, that was our yes, that was
6	not appropriate except in a highly selected	6	our opinion. If this is an accurate document, I
7	subpopulation."	7	don't see a reason why it's not, we said that
8	Do you see where that is?	8	they needed to do a lot of safety work to and
9	A. Yes, I do.	9	efficacy work to promote the drug for any, but
10	Q. And does that seem accurate to you as	10	highly selected cases of osteoarthritis.
11	well?	11	Q. Okay.
12	MR. PETRILLO: Objection.	12	MR. SNAPP: Is this a good time for a
13	MR. SNAPP: Object to the form.	13	break?
14	A. I don't reading it now, I don't	14	MS. SINGER: Let me just finish this
15	know what Purdue recognized or didn't recognize.	15	document.
16	BY MS. SINGER:	16	MR. SNAPP: Absolutely.
17	Q. Okay.	17	BY MS. SINGER:
18	A. The statement that opioids are not	18	Q. And the study included outcome
19	single entity opioids are not for general use in	19	measures related to abuse, diversion, tolerance.
20	osteoarthritis is medically, to my opinion,	20	Let's stop with those three. Do you know why
21	true.	21	those would have been elements or outcomes on
22	Q. Is what?	22	which you were focused?
23	A. To my opinion is medically true.	23	MR. SNAPP: Object to the form.
24	Q. A single entity opioid is what?	24	A. I know why now, if I can answer in the
25	A. One which does not contain another	25	present.
1		1	•
			- 10-
	Page 103		Page 105
1	analgesic agent.	1	BY MS. SINGER:
2	analgesic agent.  Q. Like acetaminophen, for instance?	2	BY MS. SINGER: Q. Sure.
2 3	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or	2 3	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and
2 3 4	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity	2 3 4	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic
2 3 4 5	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?	2 3 4 5	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids.
2 3 4 5 6	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.	2 3 4 5 6	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would
2 3 4 5 6 7	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you	2 3 4 5 6	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993?
2 3 4 5 6 7 8	analgesic agent. Q. Like acetaminophen, for instance? A. Like Tylenol or NSAIDs or Q. And OxyContin is a single entity opioid, correct? A. Yes, it is. Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term	2 3 4 5 6	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993? MR. SNAPP: Object to the form.
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2 3 4 5 6 7 8 9 10	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data	2 3 4 5 6 7 8 9 10	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993? MR. SNAPP: Object to the form. A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the
2 3 4 5 6 7 8 9 10 11	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data collection directed toward evaluation of abuse,	2 3 4 5 6 7 8 9 10 11	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993? MR. SNAPP: Object to the form. A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the chronic use of any opioid.
2 3 4 5 6 7 8 9 10 11 12	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data collection directed toward evaluation of abuse, evaluation of diversion, increased use with time	2 3 4 5 6 7 8 9 10 11 12	BY MS. SINGER:  Q. Sure.  A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids.  Q. And you answered that now. What would your answer have been in 1993?  MR. SNAPP: Object to the form.  A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the chronic use of any opioid.  BY MS. SINGER:
2 3 4 5 6 7 8 9 10 11 12 13 14	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data collection directed toward evaluation of abuse, evaluation of diversion, increased use with time (tolerance), efficacy and safety."	2 3 4 5 6 7 8 9 10 11 12 13	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993? MR. SNAPP: Object to the form. A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the chronic use of any opioid. BY MS. SINGER: Q. Okay. Which seems confirmed by the
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2 3 4 5 6 7 8 9 10 11 12 13 14	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data collection directed toward evaluation of abuse, evaluation of diversion, increased use with time (tolerance), efficacy and safety."	2 3 4 5 6 7 8 9 10 11 12 13	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993? MR. SNAPP: Object to the form. A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the chronic use of any opioid. BY MS. SINGER: Q. Okay. Which seems confirmed by the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data collection directed toward evaluation of abuse, evaluation of diversion, increased use with time (tolerance), efficacy and safety."  What do you understand this to mean?  MR. SNAPP: Object to the form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	BY MS. SINGER:  Q. Sure.  A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids.  Q. And you answered that now. What would your answer have been in 1993?  MR. SNAPP: Object to the form.  A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the chronic use of any opioid.  BY MS. SINGER:  Q. Okay. Which seems confirmed by the elements of this study?  MR. SNAPP: Object to the form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data collection directed toward evaluation of abuse, evaluation of diversion, increased use with time (tolerance), efficacy and safety."  What do you understand this to mean?  MR. SNAPP: Object to the form.  A. If an indication, a label indication in osteoarthritis is sought, then it's a big job.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993? MR. SNAPP: Object to the form. A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the chronic use of any opioid. BY MS. SINGER: Q. Okay. Which seems confirmed by the elements of this study? MR. SNAPP: Object to the form. MS. SINGER: All right. I think now is a good time for a break. THE VIDEOGRAPHER: We are now going
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	analgesic agent.  Q. Like acetaminophen, for instance?  A. Like Tylenol or NSAIDs or  Q. And OxyContin is a single entity opioid, correct?  A. Yes, it is.  Q. Okay. So last line from this, if you can look at, "If we wish to perform a long-term study in osteoarthritis patients, we should study highly selected patients. Such a study should include questionnaires and data collection directed toward evaluation of abuse, evaluation of diversion, increased use with time (tolerance), efficacy and safety."  What do you understand this to mean?  MR. SNAPP: Object to the form.  A. If an indication, a label indication in osteoarthritis is sought, then it's a big job.  BY MS. SINGER:  Q. Then it's a big?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MS. SINGER: Q. Sure. A. Abuse, diversion, tolerance, and withdrawal are always issues with the chronic use of opioids. Q. And you answered that now. What would your answer have been in 1993? MR. SNAPP: Object to the form. A. Okay. To the best of my recollection, abuse, diversion, tolerance, and withdrawal would have been important questions about the chronic use of any opioid. BY MS. SINGER: Q. Okay. Which seems confirmed by the elements of this study? MR. SNAPP: Object to the form. MS. SINGER: All right. I think now is a good time for a break. THE VIDEOGRAPHER: We are now going off the record, and the time is 11:24 a.m. (Whereupon, a recess was taken.)
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Page 106 Page 108 another exhibit, Dr. Wright. This way we go 1 Q. Yes. Is that correct? 2 home with less paper. So this is Exhibit 2 MR. SNAPP: Object to the form. 3 Number 7, it is PKY180761078. And please take a 3 A. What is written here, which says that 4 4 minute and see if you recognize this document. there would be a heavy data requirement, and 5 (Whereupon, Purdue-Wright-7 was marked that it would likely be reviewed not only by the 6 drug abuse advisory committee but the arthritis for identification.) 7 7 advisory committee is correct. (Witness reviewing document.) 8 8 BY MS. SINGER: BY MS. SINGER: 9 9 Q. The longer we're here today the Q. Okay. All right. We're going to turn 10 10 smaller the font gets. So I'm going to pose the to Exhibit 8. 11 question, whenever you're ready to answer, 11 (Whereupon, Purdue-Wright-8 was marked 12 12 please do. for identification.) 13 13 Do you recognize these to be minutes BY MS. SINGER: 14 of a meeting between Purdue Pharma and the FDA. 14 Q. And Exhibit 8 is PDD7024302094. 15 15 And if you don't recognize it, that's fine, too. A. Is this the same? Does it come apart? 16 A. I don't recognize this document. 16 MR. PETRILLO: You keep that one. 17 17 Q. Okay. I want you to turn to Bates BY MS. SINGER: 18 number 1088 and see if you are familiar with the 18 Q. And it's titled "Author: Dr. James 19 19 conversation described here. Conover." 20 20 So if you look at Paragraph 8 that Do you recognize that name? 21 21 starts Dr. Lacouture, I'm sure I didn't say that A. I've heard the name before. I'm not 22 correctly, and it says -- it's talking about an 22 sure I know who James Conover is now. 23 23 OA extension study, correct? Q. Okay. Was he at Purdue, or FDA, if 24 A. What I read here is an extension study 24 you recall? 25 25 that is proposed. A. I think he was company. I'm not sure Page 107 Page 109 1 Q. Okay. And that's related to he was Purdue. 2 2 OxyContin, correct? Q. Okay. All right. And the date of 3 3 A. I believe so. this document is 9/15/94, correct? 4 Q. Okay. And it says here that you said A. Mm-hmm. Q. And its subject is "FDA Meeting 5 -- "Dr. Wright said that while these data are 6 valuable, he would not allow advertising for the Minutes," correct? 7 management of osteoarthritis. To promote in A. Yes. 8 this area we would need several more controlled 8 Q. Okay. I want you to turn, if you 9 9 studies and then review of the data by at least will, to Bates number 2102, just towards the end 10 10 two FDA advisory panels." of the document. If you look about halfway 11 11 Do you recall having that down, why don't you read this time, if you 12 would, "Dr. Wright stated he had a little 12 conversation? 13 13 A. I do not recall having that trouble." Do you see where I am? 14 conversation. It, however, sounds like me. 14 A. Yes. "Dr. Wright stated he had a 15 15 little trouble with the claim 'the drug to start Q. Okay. 16 16 MR. PETRILLO: I think you may be with and stay with' because he was unsure of 17 17 blocking your mic. titration with OxyContin tablets. He offered 18 18 BY MS. SINGER: the idea of marketing a 10-milligram IR 19 19 Q. All right. And this is consistent oxycodone tablet to have patients titrated on first and then be switched to OxyContin." 20 again with your prior remarks, that it would be 20 21 a heavy lift or a big load, or whatever phrase 21 Q. Okay. You can stop there. 22 22 So do you recall this conversation? you used previously? 23 MR. SNAPP: Object to the form. 23 A. No, I do not. 24 A. Was that a question? 24 Q. Okay. And do you understand what this

25

language is referring to?

BY MS. SINGER:

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Page 110 Page 112 1 A. Well, I can only -- I mean, I can only NSAIDs should be excluded from a start on 2 2 say what it says in this document, which is, I OxyContin? 3 think, is likely to be correct-ish. 3 MR. SNAPP: Object to the form. 4 4 A. It wasn't my view. It was the WHO Q. Okay. 5 A. The drug to start with and stay with 5 analgesic ladder at the time. 6 sounds like a marketing phrase, and it's not --6 BY MS. SINGER: 7 7 what it says here sounds like me, and most Q. And can you explain that? 8 physicians would start with an IR drug --8 A. The World Health Organization had some 9 Q. And IR is immediate-release? 9 guidelines for pain management, and that was --10 10 A. Immediate-release drug. we called it the WHO ladder, and it was intended 11 -- and then switch to a 11 to guide physicians --12 12 controlled-release, unless the patient's MS. SINGER: Excuse me, Dr. Wright. 13 13 condition warranted going directly to a On the phone, please mute. You're 14 14 controlled-release drug. interrupting the deposition. 15 15 A. And the goal of it was to increase the Q. Okay. And is it fair to say that 16 before OxyContin was launched you were concerned 16 likelihood that the patients' benefits 17 about positioning OxyContin as the first opioid 17 outweighed the risks or adverse events. And WHO 18 18 to try? ladder has been subject to much controversy in 19 19 MR. SNAPP: Object to the form. the pain management community, but it basically 20 20 A. I truly can't remember if I was is start with non-opioid drugs, add opioid 21 concerned with it at that time. 21 drugs, then go to the heavy opioid drugs. 22 22 BY MS. SINGER: BY MS. SINGER: 23 23 Q. Okay. Let's move on to 185. Oh, Q. And in terms of your views, does that 24 we've done it before? 24 seem like the right approach? 25 25 MR. PETRILLO: Today? MS. FORSTER: Exhibit 4. Page 111 Page 113 A. Today, then, whenever? 1 MS. SINGER: Okay. 1 2 2 BY MS. SINGER: BY MS. SINGER: 3 3 Q. Why don't we start with today. Q. All right. Exhibit 4, if you could 4 4 pull that one back out, please. If you could A. Okay. As modified by who the patient 5 look in the middle of the page here, "In is and what their condition is. Ladders of that 6 exclusion criteria, Dr. Wright suggested we have type, stepped care paradigms, were extremely 7 an exclusion such as: patient excluded if he/she popular back in the '70s and '80s, first do 8 this, then do this, then do this, then do this. has satisfactory management of pain with full 9 9 dose NSAID." There was some controlled studies, which I can't 10 10 Do you see where I am? cite, I'm sorry, that showed that when 11 11 A. No. physicians were allowed to modify those stepped 12 12 Q. It's right in the middle. care protocols the outcomes were better, because 13 13 A. Which page? if you had a patient who had mild osteoarthritis 14 Q. I'm sorry, it is Bates number 185. 14 you would start with a non-steroidal. But if 15 15 A. 185. Okay. Thank you. So it's that you had a patient who had two knees that were so 16 paragraph "In exclusion criteria." 16 damaged they couldn't walk, you wouldn't start 17 17 MS. SINGER: Can whoever on the phone with -- necessarily start with a non-steroidal 18 18 be on mute, please? We're getting a lot of 19 19 background noise. Q. So again, please correct me because I 20 20 A. I see what you refer to. don't want to put words in your mouth, the 21 Q. Okay. And do you recall that 21 stepped ladder provides a baseline that should conversation? 22 22 be your starting guidepost, but you can vary 23 23 A. No, I do not. from that for particular patients where Q. Okay. And is it accurate to say your 24 24 warranted. Is that accurate as to your views? 25 25 view was that patients who were doing well on A. Could you repeat that again?

Page 114 1 Q. No. But I can read it back. opinion on this topic, because it depends on 2 A. Okay. what the pain disease -- what pain condition 3 3 you're treating. Some respond to NSAIDs Q. Which is, correct me because I don't 4 want to put words in your mouth, the stepped beautifully, some don't respond to opioids at 5 5 ladder provides a baseline that should be your all. 6 6 starting guidepost, but you can vary from that And so the WHO guidelines were rough 7 for particular patients where warranted? general guidelines that said here's a framework 8 8 A. With a change. The general approach that you can hold on to, and you need to then 9 in that period of time was to start with the WHO modify it as you need to to practice medicine 10 ladder and modify as necessary to meet the needs 10 properly. 11 of your individual patient. 11 BY MS. SINGER: 12 12 Q. Okay. And is that your view now or Q. Okay. On the same exhibit, it says --13 13 then? sorry. Let's leave this one for now. Actually 14 14 MR. SNAPP: Object to the form. sorry, let me see it again. All right. Let's 15 15 A. I decline to answer because there's turn to 563, please. 16 16 So this is Exhibit 9. It is been an enormous amount of research in the use 17 17 of opioids for pain since that time, and I am PKY180919563, it's titled "Investigator's 18 18 not familiar with all of that research and what Brochure." 19 19 their findings have been. In general I still Dr. Wright, do you recognize this 20 20 remain convinced that you should start with the document? 21 21 drug with the least risk and move up toward the (Whereupon, Purdue-Wright-9 was marked 22 riskier drugs if you need them. 22 for identification.) 23 23 BY MS. SINGER: A. No. I do not. 24 Q. Okay. And the riskier drugs would be 24 BY MS. SINGER: 25 25 the opioids? Q. Okay. Do you know what an Page 115 Page 117 MR. SNAPP: Object to the form. 1 investigator's brochure is? 2 2 A. Yes. A. Not exactly. There are -- there's --3 3 there are patients for whom NSAIDs are much Q. Okay. What is an investigator's 4 4 riskier than opioids, and NSAIDs are subject to brochure? 5 dose duration limits that opioids are not. 5 A. An investigator's brochure is a 6 People treat -- you're asking fairly statement of what is known about the 7 sophisticated medical management questions. investigational drug up to the point of the 8 There are patients for whom NSAIDs are very start of the study, or sometimes beyond if it's 9 9 toxic indeed. There are patients for whom a long study, which is provided to the 10 10 opioids are high risk indeed. And your goal, if investigator so that the investigator knows 11 you were a thoughtful physician, is to try to 11 everything that the company knows or thinks it 12 12 evaluate each single patient and say how can I knows or hopes it knows about the 13 13 manage their pain with the best chance of investigational drug before they decide to 14 getting them relief and the least chance of 14 enroll a patient in the study. 15 15 hurting them or others. O. Okay. And just to be clear, it's a 16 16 BY MS. SINGER: document provided by the company, the drug 17 17 Q. And again, just to make sure I sponsor, to the FDA, correct? 18 18 understand you, the idea is that the WHO ladder A. It is -- the IND should include a copy 19 19 is a guideline, you start with NSAIDs, you move of the investigator's brochure. 20 20 up the ladder to opioids, recognizing that for Q. Okay. Which, again, is from the 21 some patients NSAIDs may not be the right 21 company to the FDA? 22 22 choice, and for patients with more severe A. Yes.

23

24

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BY MS. SINGER:

conditions opioids may be the right choice?

A. There's not uniformity of medical

MR. SNAPP: Object to the form.

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MR. SNAPP: Object to the form.

Q. Okay. So if you can turn to Bates

	gnry Confrdential - Subject to		<b>-</b>
	Page 118		Page 120
1	number 598, please. Now, I'm sorry just to	1	Q. Okay. And who are the investigators?
2	locate this document, it's titled "Oral	2	A. The people who conduct the clinical
3	Controlled-Release Oxycodone Hydrochloride	3	studies for Purdue.
4	Tablets" on the title page, correct?	4	Q. Got it. Okay.
5	A. Oral Controlled-Release Oxycodone	5	All right. So it is Purdue's
6	Hydrochloride Tablets.	6	statement to the investigators doing the
7	Q. Under the title "OxyContin" which is	7	clinical trials and to the FDA which receives a
8	probably more descriptive?	8	copy, correct?
9	A. Yes.	9	MR. SNAPP: Object to the form.
10	Q. So this is the investigator's brochure	10	A. (Nodding in the affirmative).
11	for OxyContin, correct?	11	BY MS. SINGER:
12	A. It appears to be.	12	Q. You nodded.
13	Q. I'm sorry, now let's go to 598,	13	A. I nodded. This document should have
14	please. If you can look at the section under	14	been provided to every investigator who
15	"Abuse Liability of Oxycodone," please. And if	15	conducted a Purdue clinical trial, and a copy
16	you look down, second paragraph, "The abuse and	16	should have been submitted to the IND.
17	illegal drug trafficking," and just read that to	17	Q. Okay. By Purdue, correct?
18	yourself, please.	18	A. By Purdue.
19	(Witness reviewing document.)	19	MR. SNAPP: Object to the form.
20	BY MS. SINGER:	20	BY MS. SINGER:
21	Q. Just let me know whenever you're	21	Q. Okay. And on Page 599, the top of the
22	ready.	22	next page, if you can look at the bottom
23	And do you read this to talk about	23	sentence of the partial paragraph that starts
24	prior diversion and abuse of Percodan?	24	the page, "Furthermore, other studies have shown
25	A. I read this as a discussion of the	25	that the incidence of iatrogenic addition to
		1	
	Page 119		Page 121
1	Page 119 abuse and diversion of Percodan.	1	
1 2	abuse and diversion of Percodan.	1 2	opioid analgesics is very low (see subsequent
	_		opioid analgesics is very low (see subsequent discussion)."
2	abuse and diversion of Percodan.  Q. Okay. Which came from, according to	2	opioid analgesics is very low (see subsequent
2 3	abuse and diversion of Percodan.  Q. Okay. Which came from, according to Purdue's report, "a liberal regulation of	2 3	opioid analgesics is very low (see subsequent discussion)."  Do you see that?
2 3 4	abuse and diversion of Percodan.  Q. Okay. Which came from, according to Purdue's report, "a liberal regulation of oxycodone-containing compounds whereby 'street'	2 3 4	opioid analgesics is very low (see subsequent discussion)."  Do you see that?  A. Yes.
2 3 4 5	abuse and diversion of Percodan.  Q. Okay. Which came from, according to Purdue's report, "a liberal regulation of oxycodone-containing compounds whereby 'street' addicts could obtain Percodan more easily than	2 3 4 5	opioid analgesics is very low (see subsequent discussion)."  Do you see that?  A. Yes.  Q. Okay. And if you move down the page,
2 3 4 5 6	abuse and diversion of Percodan.  Q. Okay. Which came from, according to Purdue's report, "a liberal regulation of oxycodone-containing compounds whereby 'street' addicts could obtain Percodan more easily than morphine," correct?	2 3 4 5 6	opioid analgesics is very low (see subsequent discussion)."  Do you see that?  A. Yes.  Q. Okay. And if you move down the page, "The incidence of narcotic addiction," very last
2 3 4 5 6 7	abuse and diversion of Percodan.  Q. Okay. Which came from, according to Purdue's report, "a liberal regulation of oxycodone-containing compounds whereby 'street' addicts could obtain Percodan more easily than morphine," correct?  MR. SNAPP: Object to the form.	2 3 4 5 6	opioid analgesics is very low (see subsequent discussion)."  Do you see that?  A. Yes.  Q. Okay. And if you move down the page, "The incidence of narcotic addiction," very last paragraph, "was obtained by the Boston
2 3 4 5 6 7 8	abuse and diversion of Percodan.  Q. Okay. Which came from, according to Purdue's report, "a liberal regulation of oxycodone-containing compounds whereby 'street' addicts could obtain Percodan more easily than morphine," correct?  MR. SNAPP: Object to the form.  A. That's what it says.  BY MS. SINGER:  Q. Okay. And that "Percodan was easily	2 3 4 5 6 7 8	opioid analgesics is very low (see subsequent discussion)."  Do you see that?  A. Yes.  Q. Okay. And if you move down the page, "The incidence of narcotic addiction," very last paragraph, "was obtained by the Boston Collaborative Drug Surveillance Program from
2 3 4 5 6 7 8 9 10	abuse and diversion of Percodan.  Q. Okay. Which came from, according to Purdue's report, "a liberal regulation of oxycodone-containing compounds whereby 'street' addicts could obtain Percodan more easily than morphine," correct?  MR. SNAPP: Object to the form.  A. That's what it says.  BY MS. SINGER:  Q. Okay. And that "Percodan was easily boiled into a solution by the 'street' addict	2 3 4 5 6 7 8 9 10	opioid analgesics is very low (see subsequent discussion)."  Do you see that?  A. Yes.  Q. Okay. And if you move down the page, "The incidence of narcotic addiction," very last paragraph, "was obtained by the Boston Collaborative Drug Surveillance Program from their files on 39,946 hospitalized patients," and it cites Porter and Jick, 1980.  Are you familiar with that study?
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Page 122 Page 124 1 BY MS. SINGER: A. If these documents are accurate, I 2 made it very clear that we didn't want to see Q. Exhibit 10 is PKY181876119, and it is 3 narcotics as the primary therapy for unselected titled "Regulatory Barriers to Effective Pain 4 4 Management." patients with osteoarthritis. We didn't want to 5 5 I take it you don't recall having seen see an osteoarthritis indication. 6 6 this document, is that correct? (Whereupon, Purdue-Wright-11 was 7 7 marked for identification.) A. No, I don't remember this document at 8 8 all. BY MS. SINGER: 9 9 Q. Okay. Do you recognize the name Q. We're at Exhibit 11, PKY180723482, 10 10 titled Project Team Contact. We've done this R. Kaiko? 11 A. Bob Kaiko. 11 one. That's my fault. We've done this one. My 12 12 apologies. Let's go to 232. O. Kaiko. 13 (Whereupon, Purdue-Wright-12 was 13 A. Yes, Bob Kaiko was a scientist at 14 14 Purdue. marked for identification.) 15 15 Q. What about M. Innaurato? BY MS. SINGER: 16 16 Q. So Exhibit 11 is going to be blank, A. I have heard the name. I can't place 17 17 and we'll just move to Exhibit 12. And that is it with a face, and I don't know what he did. 18 Q. Okay. I want to direct you, if I 18 PDD1701503232 titled Meeting Minutes. 19 19 might, to Bates number 258 -- I'm sorry, And, Dr. Wright, do you see your name 20 actually 257, which I think in the PKY is 120. listed as an FDA representative? 20 21 21 A. Yes, I do. And the last paragraph talks about 22 22 Q. Okay. And do you have any "Perhaps even more importantly, with the 23 23 recollection of a June 23rd, '93, 1993, meeting movement of our scheduled analgesics to 24 non-cancer pain (with the introduction of 24 with Purdue? 25 25 DHCplus and the coming introduction of A. I don't have any recollection Page 123 Page 125 OxyContin), we cannot help but believe these immediately. I'm trying to see if this 1 refreshes my recollection. 2 regulatory and legal barriers will pose 2 3 substantial impediments." 3 Q. Okay. 4 Do you see where I've read? 4 (Witness reviewing document.) Q. If it's helpful, I can direct you to a 5 A. Yes. 6 Q. Do you recall Purdue ever talking to particular piece of this and see if that 7 you about moving OxyContin into the non-cancer refreshes your recollection. So if you want to 8 pain patient? go, please, to Bates number 238. And if you 9 9 MR. SNAPP: Object to the form. look at Section 2, "Nonclinical Toxicology." 10 10 A. I don't remember Purdue talking about Do you see where that is? 11 that as a goal for OxyContin. 11 A. (Nodding in the affirmative). BY MS. SINGER: 12 12 Q. It says here that "It was also agreed 13 Q. And did you ever become aware of that 13 that oxycodone is an old drug in which the human 14 as a goal for OxyContin? 14 toxicity profile is well-known." 15 15 MR. SNAPP: Object to the form. Do you see that sentence? 16 A. Ever. In some of the previous 16 MR. SNAPP: Object to the form. 17 17 documents it -- I never looked -- I never A. Yes, I see that. 18 formulated it that way, I never -- I just don't 18 BY MS. SINGER: 19 19 know. Q. And do you agree with that statement 20 20 BY MS. SINGER: that "oxycodone is an old drug in which the 21 21 human toxicity profile is well-known"? Q. And if you didn't formulate it that 22 22 A. Agree now, or agreed then? way, was there a different way that you 23 formulated it? 23 Q. Start with now. 24 A. If these documents --24 A. I agree. 25 25 Q. And did you agree back in 1993 when MR. SNAPP: Object to the form.

Page 126 1 this meeting happened? 1 population matters and is considered as part of 2 2 MR. SNAPP: Object to the form. the safety profile for a new drug. At the time 3 3 MR. PETRILLO: Just for the record, it I remember being concerned about abuse of 4 doesn't appear that at this portion of the OxyContin, we all were, but we had no notion 5 meeting Dr. Wright was present, according to the that the society had changed to the point where 6 minutes. the 40 and the 80-milligram OxyContin products 7 7 A. I don't remember the meeting, and I would be so desirable for purposes of diversion. 8 8 I don't know if that's a long painful don't know whether I was present or not. You 9 9 were asking an independent question from my answer to what you had to say. Oxycodone we 10 10 clinical opinion. knew about. We knew what oxycodone safety was 11 BY MS. SINGER: 11 like and what was likely to happen. OxyContin, 12 12 the drug product as marketed, we weren't O. That's right. 13 13 thinking that way in 1990, '95. A. Both then and now I believe the 14 14 toxicity profile of oxycodone is well-known. BY MS. SINGER: 15 15 Q. And do you believe that that's true at Q. Okay. If we can go back to Exhibit 12 16 all of the different dosage forms of oxycodone? 16 for a moment, that's the one that's 232, maybe 17 17 MR. SNAPP: Object to the form. the one we have right now. And if you could 18 18 BY MS. SINGER: turn to Bates number 239, which is the next page 19 19 Q. Meaning, in 1993 was the human from where we were, and if you could look under 20 20 Paragraph 3, "Toxicology of Abuse." toxicity profile of OxyContin at 40 milligrams 21 well-known? 21 Do you see that at the top of the 22 22 MR. SNAPP: Object to the form. page? 23 23 A. In -- I'm still not understanding what A. Mm-hmm. 24 is it that you want to know. 24 Q. And could you read that first 25 25 BY MS. SINGER: sentence, please? Page 127 Page 129 1 Q. Whether there was a body of knowledge 1 A. "Toxicology of Abuse: The FDA was 2 2 or evidence about the toxicology of OxyContin at concerned about pulmonary microemboli and 3 40 milligrams when the drug was submitted for 3 granulomas which may occur when oral 4 approval. preparations such as this are extracted and 5 MR. SNAPP: Object to the form. 5 injected intravenously by abusers." 6 A. I certainly believed so at the time. 6 Q. You can stop there, just the first 7 7 BY MS. SINGER: sentence. 8 8 Q. And do you believe that now? Do you recall having this conversation 9 9 A. I don't know, because circumstances with Purdue Pharma? 10 have changed between then and now. 10 A. Vaguely. We always were concerned 11 Q. In what way? 11 about excipients. 12 12 Q. About? MR. SNAPP: Object to the form. 13 13 A. Well, a lot of ways. But in 1980, A. Excipients. 14 '85, '90, the focus of safety as defined by the 14 Q. And can you explain what that is? 15 15 agency for a pharmaceutical was safety used as A. There were some products, and I cannot 16 16 directed by a medical practitioner. The notion remember their names, they were narcotics, where 17 17 of pharmacoepidemiology, what are the safety the company used a binder for the tablets that 18 18 results in the population as vended and sold by contained a variety of foreign materials called 19 19 the population, was emerging but was not a fully excipients which held the tablet together. Talc

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developed principle then, I don't think the

I don't know for sure what the timing was.

Today, by today's standards, what

happens when the drug interacts with a specific

pharmacoepidemiology were fully developed then.

guidances on pharmacovigilance and

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in particular was particularly problematic

because if it was injected intravenously it

the lungs of abusers.

could cause significant granulomatous damage to

was talking to Purdue Pharma back in 1993 about

Q. Okay. So this reflects that the FDA

Page 130 Page 132 1 the risks associated with injection of 1 MR. SNAPP: Object to the form. 2 OxyContin, is that correct? 2 BY MS. SINGER: 3 MR. SNAPP: Object to the form. 3 Q. -- when injected? 4 4 A. It was -- yes, I think so. A. That is so hard to answer, because it 5 depends on the state of opioid tolerance of the BY MS. SINGER: 6 individual. But for a naive user who has not Q. Okay. And did the extended-release, 7 the controlled-release profile of OxyContin have had any opioids, injecting 40 milligrams or 8 any impact on how the FDA or how you, how you, 80 milligrams of oxycodone would be a very 9 assessed the risk or likelihood that users would strong dose, very strong, and severe. 10 10 inject OxyContin? Q. All right. And moving to the next 11 MR. SNAPP: Object to the form. 11 paragraph which is somewhat bolded, "As part of 12 12 A. Can you sharpen that up a little bit? the June 30 telephone conversation" -- do you 13 13 Because that is such a -- "have any," that is see where I am on 239, Dr. Hayes -- "between 14 14 such a vague question. Dr. Hayes and Dr. Tigner"? 15 15 BY MS. SINGER: A. Mm-hmm. 16 Q. Did you think that the 16 Q. "It was agreed that oxycodone HCl" --17 17 controlled-release formulation would make it is that OxyContin. A. That's oxycodone hydrochloride, the 18 more attractive for users to inject OxyContin? 18 19 19 A. I did not think that the parent drug substance. 20 20 controlled-release formulation would make the Q. Okay. 21 product more attractive. We were concerned 21 -- "is very soluble in water, a fact 22 22 which abusers would most likely learn very about the tablet size. 23 23 Q. Okay. What about the potency of the auickly." 24 tablets, did you think that would have any 24 Do you remember this conversation --25 impact on the likelihood of intravenous use? did you ever hear about this conversation? Page 131 Page 133 1 A. I don't remember whether I heard about 1 A. I'm confused --2 2 MR. SNAPP: Object to the form. it or not. 3 3 A. -- because you used the word Q. And are you aware of the water 4 "potency." That has a specific technical 4 solubility of oxycodone hydrochloride? A. Very much so. 5 meaning. 5 6 BY MS. SINGER: Q. And was that something that you thought about and discussed with Purdue Pharma 7 Q. Which I'm sure I didn't intend. 8 at the time? A. We were concerned about the amount of 9 9 drug in the tablet. A lot of drug in a tablet. MR. SNAPP: Object to the form. 10 10 Q. Okay. A. I don't know if I discussed it or not, 11 A. Make it attractive, a lot of drug. 11 because all drugs of that class that I know of, 12 12 Q. And is there a lot of drug at the semi-synthetic narcotics of that era and 80 milligrams of OxyContin? 13 13 age, are water soluble, that they were developed 14 A. There is a lot of drug --14 to be water soluble. Did I discuss with -- the 15 MR. SNAPP: Object to the form. 15 fact with Purdue that their drug could be cooked 16 A. -- at 80 milligrams of OxyContin, 16 and shot, injected for abuse? I'm almost 17 17 80 milligrams. certain I didn't. 18 18 BY MS. SINGER: BY MS. SINGER: 19 19 Q. And is there a lot at 40 milligrams? Q. Okay. All right. If we could turn to 20 Bates number 3241, also the top of the page. 20 MR. SNAPP: Object to the form. 21 A. Immediate-release opioids of the 21 A. 3241? 22 period had 5, maybe 10 milligrams. 22 Q. 3241. It's the next page, I think. 40 milligrams is four times as much. 23 23 You'll see Paragraph 6, "Higher Dosage Strengths 24 BY MS. SINGER: 24 - Adverse Event Profile Concerns." And can you 25 25 read aloud through "opioid tolerant patients Q. Is it enough to produce euphoria --

Page 134 Page 136 1 only"? So the first two sentences, I believe. 1 Q. Yes. Please. 2 2 A. "Combination product: PF should A. "Because oxycodone IR 5 milligrams is 3 the current marketed product there is concern 3 consider an OxyContin Tablets/Naloxone about the adverse event profile of higher dosage 4 4 combination as a supplement to the NDA." 5 strengths (40, 80, 160) are administered to 5 O. So do you recall this conversation 6 opiate naive patients. Suggestion that PF 6 with Purdue? 7 7 consider including a 'red triangle (opioid A. I don't recall it. I have no reason 8 tolerant only)' on the packaging of the 40, 80 8 to think I didn't do it. 9 9 and 160-milligram dosage strengths to indicate Q. Okay. And why would -- why would you 10 10 that these dosage strengths be administered to have recommended to Purdue that it consider an 11 opioid tolerant patients only." 11 OxyContin/naloxone combination? 12 12 Q. You can stop there. MR. SNAPP: Object to the form. 13 13 Do you remember that conversation? A. It is clear -- it was clear to us 14 14 A. Not specifically, but I remember the then, it is clear to us now, it is clear to me 15 15 red triangle. now that this product was vulnerable to 16 Q. And what do you remember about that? 16 tampering and injection. If you made an 17 17 A. Okay. It was what we negotiated and oxycodone/naloxone combination, the naloxone 18 18 was launched under gesic, I mentioned earlier in would spoil the oxycodone by acting as an 19 19 the discussion that we wanted some kind of antagonist, and it could not be injected. 20 20 distinctive marking hopefully common across Looking back, based on my experience 21 manufacturers that indicated to prescribers that 21 since that time, that was an easy thing to ask 22 this was a high strength. 22 for and an extraordinarily difficult thing to 23 23 Q. Okay. And what were your concerns at 24 higher dose strengths? 24 BY MS. SINGER: 25 25 A. There would -- that someone would Q. Understanding that, it certainly Page 135 Page 137 1 overdose. reflects an awareness back in 1993 that 2 2 injection was going to be a problem, correct? Q. And do you know as we sit here what 3 the morphine equivalent dose of 40 milligrams of 3 MR. SNAPP: Object to the form. 4 OxyContin taken twice a day as directed is? 4 A. Is that a question? 5 A. Not anymore. I used to. 5 BY MS. SINGER: 6 Q. Okay. And do you recall thinking that 6 Q. Yes. 7 the 40, 80 and 160-milligram dosage strengths 7 MR. SNAPP: Object to the form. 8 should have that red triangle? 8 A. Okay. Could you restate it, please, 9 9 MR. SNAPP: Object to the form. simply? 10 A. I do not recall that specifically. 10 BY MS. SINGER: 11 This memorandum suggests that that's what I 11 O. Sure. 12 12 thought at the time. So the recommendation that Purdue 13 13 BY MS. SINGER: consider an OxyContin/naloxone combination 14 Q. And does that seem accurate and 14 reflects a recognition that there was going to 15 15 consistent with your beliefs? be use by injection? 16 A. Seems accurate and consistent with my 16 MR. SNAPP: Object to the form. 17 17 beliefs. Somewhere -- and I don't know whether A. It's still a statement, not a 18 18 it would be 40 or 60 or whether it should just question. 19 19 be the 80 and 160, I wasn't certain, but I knew BY MS. SINGER: 20 20 that past a certain point those tablets should Q. Correct. Is that right? 21 be only going into opioid tolerant patients. 21 MR. SNAPP: Object to the form.

22

23

24

25

A. Yes. Would you like me to?

"Combination Product"?

Q. If we can move down on the same page

to Paragraph 13, can you read what it says by

22

23

24

25

A. From the earliest point through the

was never any illusions on the agency's part

that this was a product that could develop an

final approval of oxycodone, OxyContin, there

Page 138 1 abuse problem. Never any question. it correct that OxyContin was what's called a 2 2 (Whereupon, Purdue-Wright-13 was non-NME drug review? 3 3 marked for identification.) A. Yes. 4 4 BY MS. SINGER: Q. Okay. And can you explain what that 5 5 means? Q. So this is Exhibit 13, PDD 150 -- I'm 6 6 sorry, SHC-00007028. And it is "Subject: FDA A. There are -- there's no official 7 OxyContin Tablets Meeting." difference between any of the kinds of 8 8 Dr. Wright, are you familiar with this applications that are sent into the agency 9 9 document? except some of the more modern changes, but the 10 10 agency broadly split as a matter of policy drugs A. I don't know that I've ever seen it. 11 Q. Okay. Do you see yourself listed 11 into two classes. New molecular entities that 12 12 among the FDA attendees on the first page? had not been in man, that's an NME, or drugs 13 13 A. Yes, I do. that had been in man in some form and had an 14 14 Q. Okay. And can you see among the "To" established toxicity record, non-NME. 15 15 line here that this memo was circulated to M.D. Q. And was the level of scrutiny or the 16 Sackler, R.R. Sackler, R.S. Sackler, K.A. 16 bar to approval different between NME and 17 17 Sackler, J.D. Sackler? non-NME drugs? 18 18 A. Yes. A. That's what the addressees say. 19 19 Q. From your time at Purdue, was it Q. In what way? 20 common to send the Sacklers information about 20 A. For a non-NME product you were looking 21 21 FDA meetings? to look for unanticipated adverse events at, 22 MR. SNAPP: Object to the form. 22 say, the 1 percent level. For an NME you were 23 23 A. I don't know what was sent to the looking at -- trying to look at, say, the tenth 24 Sacklers and what was not. 24 of a percent level, you needed more patients, 25 25 BY MS. SINGER: longer studies, more time, more toxicology, Page 141 Page 139 Q. Okay. Now, in the first paragraph on ancillary studies of several different kinds to 1 1 2 2 the first page below the tos and attendance look for unusual or unanticipated toxicity. An 3 3 lists, it describes the pilot division of the example would be that there's now screening for 4 FDA and the NDA process, is that correct? 4 certain kinds of cardiac effects that did not 5 A. Yes. 5 exist at this time. 6 Q. Okay. And was this pilot process So an NME gets a lot longer period of 7 different from other opioid approvals you'd been 7 scrutiny, a lot longer period of tests, and a 8 involved in before? 8 lot more patients in the NDA. 9 9 A. No. Q. So we can just do one more document, 10 Q. It was the same pilot process, is that 10 and then if it's a good time to break for lunch. 11 11 (Whereupon, Purdue-Wright-14 was correct? 12 12 A. Well, with a caveat. The goal of the marked for identification.) 13 pilot drug evaluation staff was to pilot new 13 BY MS. SINGER: 14 approaches to the review process to improve its 14 Q. So Exhibit 14 is PDD1501090043 titled 15 15 quality and efficiency. So therefore, as we "Medical Officer Review." And do you recognize 16 learned from one NDA to the next what worked and 16 this document? 17 17 what didn't work, or there were technical A. This looks like my medical officer 18 18 changes in the technological environment so that summary review of OxyContin. 19 19 we could do things that we couldn't do before, Q. Okay. And you're listed as the 20 like use computers in the review process, use 20 reviewer, correct? 21 telecommunications for meetings instead of 21 A. I'm listed as the reviewer in this 22 22 having them in face-by-face, we would one. 23 23 incorporate that. So did it change over time? Q. Okay. So if you can turn to -- I'm 24 Yes. Was it the same process pretty much? Yes. 24 sorry, the first page, so it starts halfway down

25

Q. Okay. And are you aware that, or is

25

-- or it doesn't start, but halfway down the

	Page 142		Page 144
1	first page where it says "Background. Oxycodone	1	MR. SNAPP: Object to the form.
2	is an old opioid that's been on the market for	2	BY MS. SINGER:
3	many years in pre-38, USP, brand and generic	3	Q. What does that mean?
4	immediate-release forms as a QID drug both	4	A. What is an extreme value? When you're
5	singly and in fixed combinations with NSAIDs."	5	doing a pharmacokinetic study and you're giving
6	So could you explain that sentence,	6	the drug to individuals, some people will on
7	unpack some of those acronyms, please? So	7	some occasions for some reason that we don't
8	pre-38.	8	understand have an extremely high value or an
9	A. Pre-38, it was on some form of it	9	extremely low value. You look at those because
10	was on the market prior to 1938.	10	the extremely low value suggests the drug would
11	Q. Okay. And USP?	11	not be working. And the extremely high value
12	A. The USP has a US Pharmacopeia standard	12	suggests that the drug would be working too
13	for the drug for purity and potency.	13	well.
14	Q. And so there's been both brand and	14	Q. Okay. And so can you explain what
15	generic versions, correct?	15	you're saying in this sentence for the layperson
16	A. It says brand and generic.	16	is that the peak trough, middle, and outliers
17	Q. And then a QID drug?	17	are relatively similar between immediate-release
18	A. Four times a day.	18	and extended-release oxycodone?
19	Q. And then "singly and in fixed	19	MR. SNAPP: Object to the form.
20	combinations of NSAIDs" mean that they're both	20	A. What I'm saying at this point is the
21	single entity opioids and then combination	21	peak trough and outliers appeared to be similar.
22	opioids, correct?	22	BY MS. SINGER:
23	A. That was my understanding at the time.	23	Q. Okay. And then if we can turn to
24	Q. Okay. So what you're saying here, and	24	Page 56, or Bates number 56.
25	again correct me as I know you will, that this	25	MS. SINGER: I have an extra copy if
1	Page 143	1	Page 145
1	Page 143 is a drug that's been around for decades?	1	Page 145 somebody wants it (handing).
2	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form.	2	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue
2 3	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER:	2 3	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"?
2 3 4	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct?	2 3 4	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again?
2 3 4 5	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around	2 3 4 5	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page.
2 3 4 5 6	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades.	2 3 4 5 6	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it.
2 3 4 5 6 7	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number	2 3 4 5 6 7	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do
2 3 4 5 6 7 8	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of	2 3 4 5 6 7 8	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin?
2 3 4 5 6 7 8	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with	2 3 4 5 6 7 8	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin? MR. SNAPP: Object to the form.
2 3 4 5 6 7 8 9	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values	2 3 4 5 6 7 8 9	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin? MR. SNAPP: Object to the form. A. I'd have to refer to the package
2 3 4 5 6 7 8 9 10	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations."	2 3 4 5 6 7 8 9 10	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin? MR. SNAPP: Object to the form. A. I'd have to refer to the package insert.
2 3 4 5 6 7 8 9 10 11	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading?	2 3 4 5 6 7 8 9 10 11	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin? MR. SNAPP: Object to the form. A. I'd have to refer to the package insert. BY MS. SINGER:
2 3 4 5 6 7 8 9 10 11 12	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am.	2 3 4 5 6 7 8 9 10 11 12	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin? MR. SNAPP: Object to the form. A. I'd have to refer to the package insert. BY MS. SINGER: Q. Okay. It may say so here.
2 3 4 5 6 7 8 9 10 11 12 13 14	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you	2 3 4 5 6 7 8 9 10 11 12 13 14	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin? MR. SNAPP: Object to the form. A. I'd have to refer to the package insert. BY MS. SINGER: Q. Okay. It may say so here. All right. So you can see the last
2 3 4 5 6 7 8 9 10 11 12 13 14	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you explain what that's referring to?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Page 145 somebody wants it (handing). Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"? A. What page again? Q. Bates number 56, very last page. A. Yes. I see it. Q. And before I ask you about that, do you recall what the dosing is for OxyContin? MR. SNAPP: Object to the form. A. I'd have to refer to the package insert. BY MS. SINGER: Q. Okay. It may say so here. All right. So you can see the last paragraph, "Overall Conclusion," can you read
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you explain what that's referring to? A. Immediate-release and	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Page 145 somebody wants it (handing).  Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"?  A. What page again?  Q. Bates number 56, very last page.  A. Yes. I see it.  Q. And before I ask you about that, do you recall what the dosing is for OxyContin?  MR. SNAPP: Object to the form.  A. I'd have to refer to the package insert.  BY MS. SINGER:  Q. Okay. It may say so here.  All right. So you can see the last paragraph, "Overall Conclusion," can you read the last sentence? And you can read it out
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you explain what that's referring to? A. Immediate-release and controlled-release oxycodone given in these	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Page 145 somebody wants it (handing).  Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"?  A. What page again?  Q. Bates number 56, very last page.  A. Yes. I see it.  Q. And before I ask you about that, do you recall what the dosing is for OxyContin?  MR. SNAPP: Object to the form.  A. I'd have to refer to the package insert.  BY MS. SINGER:  Q. Okay. It may say so here.  All right. So you can see the last paragraph, "Overall Conclusion," can you read the last sentence? And you can read it out loud.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you explain what that's referring to? A. Immediate-release and controlled-release oxycodone given in these doses appeared to have similar peak and trough	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Page 145 somebody wants it (handing).  Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"?  A. What page again?  Q. Bates number 56, very last page.  A. Yes. I see it.  Q. And before I ask you about that, do you recall what the dosing is for OxyContin?  MR. SNAPP: Object to the form.  A. I'd have to refer to the package insert.  BY MS. SINGER:  Q. Okay. It may say so here.  All right. So you can see the last paragraph, "Overall Conclusion," can you read the last sentence? And you can read it out loud.  A. "This product has been shown to be as
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you explain what that's referring to? A. Immediate-release and controlled-release oxycodone given in these doses appeared to have similar peak and trough concentrations.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Page 145 somebody wants it (handing).  Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"?  A. What page again?  Q. Bates number 56, very last page.  A. Yes. I see it.  Q. And before I ask you about that, do you recall what the dosing is for OxyContin?  MR. SNAPP: Object to the form.  A. I'd have to refer to the package insert.  BY MS. SINGER:  Q. Okay. It may say so here.  All right. So you can see the last paragraph, "Overall Conclusion," can you read the last sentence? And you can read it out loud.  A. "This product has been shown to be as good as current therapy, bu has not been shown
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you explain what that's referring to? A. Immediate-release and controlled-release oxycodone given in these doses appeared to have similar peak and trough concentrations. Q. Okay. And those are the words we	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Page 145 somebody wants it (handing).  Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"?  A. What page again?  Q. Bates number 56, very last page.  A. Yes. I see it.  Q. And before I ask you about that, do you recall what the dosing is for OxyContin?  MR. SNAPP: Object to the form.  A. I'd have to refer to the package insert.  BY MS. SINGER:  Q. Okay. It may say so here.  All right. So you can see the last paragraph, "Overall Conclusion," can you read the last sentence? And you can read it out loud.  A. "This product has been shown to be as good as current therapy, bu has not been shown to have a significant advantage beyond reduction
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Page 143 is a drug that's been around for decades? MR. SNAPP: Object to the form. BY MS. SINGER: Q. Correct? A. This is a drug that has been around for decades. Q. Okay. And let's turn to Bates number 45, so the next page. The first paragraph of text, "Both treatments appear to be similar with respect to peak, trough, mean and extreme values in clinical populations." Do you see where I'm reading? A. Yes, ma'am. Q. Okay. So both treatments, can you explain what that's referring to? A. Immediate-release and controlled-release oxycodone given in these doses appeared to have similar peak and trough concentrations. Q. Okay. And those are the words we talked about earlier, and what they mean in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Page 145 somebody wants it (handing).  Q. Do you see the section titled "Rescue Use (Supplemental Analgesic)"?  A. What page again?  Q. Bates number 56, very last page.  A. Yes. I see it.  Q. And before I ask you about that, do you recall what the dosing is for OxyContin?  MR. SNAPP: Object to the form.  A. I'd have to refer to the package insert.  BY MS. SINGER:  Q. Okay. It may say so here.  All right. So you can see the last paragraph, "Overall Conclusion," can you read the last sentence? And you can read it out loud.  A. "This product has been shown to be as good as current therapy, bu has not been shown to have a significant advantage beyond reduction in frequency of dosing."

Q. Okay. And extreme values?

25

I have no reason to doubt that I wrote this.

	D 146		D 140
	Page 146		Page 148
1	Q. Okay. Okay. And would it refresh	1	AFTERNOON SESSION
2	your recollection, and if it doesn't it doesn't,	2	
3	that OxyContin is a 12-hour drug?	3	THE VIDEOGRAPHER: We are now going
4	MR. SNAPP: Object to the form.	4	back on the record, and the time is 1:30 p.m.
5	A. That's what it says here, BID drug.	5	BY MS. SINGER:
6	BY MS. SINGER:	6	Q. All right. Dr. Wright, I'm just
7	Q. BID. There you have it.	7	reminding you you're still under oath as we
8	What does BID stand for?	8	resume. And we'll start with Exhibit 15.
9	A. Twice a day, 12 hours.	9	(Whereupon, Purdue-Wright-15 was
10	Q. So if you go back to Rescue Use, it	10	marked for identification.)
11	indicates at the last sentence there "Patients	11	BY MS. SINGER:
12	used about 1 to 2 doses of rescue a day and	12	Q. So Exhibit 15 is Bates number SHC-8168
13	found it an important part of therapy."	13	and it's titled "Project Team Contact Report."
14	Do you see where I'm reading?	14	Is this document familiar to you,
15	A. Yes.	15	Dr. Wright?
16	Q. What is a rescue dose?	16	A. I don't recognize this document.
17	A. Okay. A rescue dose of an	17	Q. Okay. It indicates that it is the
18	immediate-release analgesic, or any analgesic,	18	record of a contact between Dr. Reder from
19	is used when the quality of pain control has	19	Purdue and you at FDA.
20	become unacceptable. If you give somebody in	20	Does that seem right?
21	general, this is what I was taught. If you give	21	A. That's what it says.
22	somebody enough analgesic so that they never	22	Q. Okay. And if you could take a moment,
23	have pain during the day, then there will be	23	the reason for the call indicates "Discuss
24	times during the day when they are	24	OC93-0704 - Package Insert Testing Study."
25	inappropriately narcotized. So it is considered	25	Do you recall the package insert
	mappropriately narcotized. So it is considered		Do you recan the package insert
	Page 147		Page 149
1	Page 147 a normal part of round-the-clock opioid therapy	1	Page 149 testing study?
1 2	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then	1 2	_
	a normal part of round-the-clock opioid therapy		testing study?
2	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in	2	testing study?  A. I don't remember it at this time. I
3	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can	2 3	testing study?  A. I don't remember it at this time. I know what package insert testing studies are.
2 3 4	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in	2 3 4	testing study?  A. I don't remember it at this time. I know what package insert testing studies are.  Q. And what are they?
2 3 4 5	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in the car or out of the car to go to the hospital,	2 3 4 5	testing study?  A. I don't remember it at this time. I know what package insert testing studies are.  Q. And what are they?  A. It's where you take physicians who are
2 3 4 5 6	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in the car or out of the car to go to the hospital, anything that might happen, you then can give	2 3 4 5 6	testing study?  A. I don't remember it at this time. I know what package insert testing studies are.  Q. And what are they?  A. It's where you take physicians who are likely to prescribe the product and you give
2 3 4 5 6 7	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in the car or out of the car to go to the hospital, anything that might happen, you then can give the immediate-release as part of the	2 3 4 5 6	testing study?  A. I don't remember it at this time. I know what package insert testing studies are.  Q. And what are they?  A. It's where you take physicians who are likely to prescribe the product and you give them the package insert, and then you ask them
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2 3 4 5 6 7 8 9	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in the car or out of the car to go to the hospital, anything that might happen, you then can give the immediate-release as part of the breakthrough, as part of the treatment.  Q. Okay. I think that's all I have.  MS. SINGER: We can take a break.	2 3 4 5 6 7 8 9	A. I don't remember it at this time. I know what package insert testing studies are. Q. And what are they? A. It's where you take physicians who are likely to prescribe the product and you give them the package insert, and then you ask them relevant questions about using the product. Q. Okay. And that goes back to, I think, and correct me if I'm wrong, your point earlier
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in the car or out of the car to go to the hospital, anything that might happen, you then can give the immediate-release as part of the breakthrough, as part of the treatment.  Q. Okay. I think that's all I have.  MS. SINGER: We can take a break.  THE VIDEOGRAPHER: We are now going off the record, and the time is 12:39.  (Whereupon, a luncheon recess was	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I don't remember it at this time. I know what package insert testing studies are.  Q. And what are they?  A. It's where you take physicians who are likely to prescribe the product and you give them the package insert, and then you ask them relevant questions about using the product.  Q. Okay. And that goes back to, I think, and correct me if I'm wrong, your point earlier that the goal of the package insert is to inform prescribers about the uses, risks, benefits, administration, all of those aspects of a prescription drug, is that correct?  MR. SNAPP: Object to the form.  A. Do you wish me to restate it?  BY MS. SINGER:  Q. Either agree with it or put it in words that you can agree to.  A. The package insert informs physicians how to use the product.  Q. Okay. And it says here and this
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in the car or out of the car to go to the hospital, anything that might happen, you then can give the immediate-release as part of the breakthrough, as part of the treatment.  Q. Okay. I think that's all I have.  MS. SINGER: We can take a break.  THE VIDEOGRAPHER: We are now going off the record, and the time is 12:39.  (Whereupon, a luncheon recess was	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I don't remember it at this time. I know what package insert testing studies are.  Q. And what are they?  A. It's where you take physicians who are likely to prescribe the product and you give them the package insert, and then you ask them relevant questions about using the product.  Q. Okay. And that goes back to, I think, and correct me if I'm wrong, your point earlier that the goal of the package insert is to inform prescribers about the uses, risks, benefits, administration, all of those aspects of a prescription drug, is that correct?  MR. SNAPP: Object to the form.  A. Do you wish me to restate it?  BY MS. SINGER:  Q. Either agree with it or put it in words that you can agree to.  A. The package insert informs physicians how to use the product.  Q. Okay. And it says here and this relates to OxyContin, correct?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	a normal part of round-the-clock opioid therapy to have both your round-the-clock drug and then during episodes of breakthrough pain, which can occur with toileting, mobility, having to get in the car or out of the car to go to the hospital, anything that might happen, you then can give the immediate-release as part of the breakthrough, as part of the treatment.  Q. Okay. I think that's all I have.  MS. SINGER: We can take a break.  THE VIDEOGRAPHER: We are now going off the record, and the time is 12:39.  (Whereupon, a luncheon recess was	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I don't remember it at this time. I know what package insert testing studies are.  Q. And what are they?  A. It's where you take physicians who are likely to prescribe the product and you give them the package insert, and then you ask them relevant questions about using the product.  Q. Okay. And that goes back to, I think, and correct me if I'm wrong, your point earlier that the goal of the package insert is to inform prescribers about the uses, risks, benefits, administration, all of those aspects of a prescription drug, is that correct?  MR. SNAPP: Object to the form.  A. Do you wish me to restate it?  BY MS. SINGER:  Q. Either agree with it or put it in words that you can agree to.  A. The package insert informs physicians how to use the product.  Q. Okay. And it says here and this

e: <u>1</u> :	17-md-02804-DAP Doc#: 2177-20 Filed	: <b>Q</b>	3/12/19 39 of 84 PageID #: 322565 urther Confidentiality Review
	Page 150		Page 152
1	Q. And can you read what it says about	1	sometimes it was not. To understand this, I'd
2	the package insert testing study under the	2	have to know what the non-compliance was, and if
3	"Results of a recent study showed"?	3	it posed a threat to patients.
4	A. "One half of the physicians did not	4	BY MS. SINGER:
5	dose according to the package insert.	5	Q. Okay. So we're going to go back, I
6	98 percent of the physicians ignored some of the	6	think it's Exhibit 4, but I'm just guessing.
7	precautionary information in the package insert.	7	14, sorry, Exhibit 14. Your medical officer
8	And a previously unrecognized disease/treatment	8	report.
9	interaction was seen."	9	A. It's half the medical officer report,
10	Q. Go ahead, if you can finish out that	10	I think.
11	last sentence.	11	Q. And do you want to explain what you
12	A. "Because of our substantial database,	12	mean by that? This is the report relating to
13	Dr. Wright would not anticipate major new	13	A. This is the integrated summary of
14	findings but asked that we continue the program	14	efficacy. There should be somewhere a
15	for now."	15	integrated summary of safety.
16	Q. Okay. So does this refresh your	16	Q. Okay. I want to return to the last
17	recollection about this, conversation or this	17	page of the document, 056, I think you read this
18	study?	18	earlier. But you wrote, "Care should be taken
19	A. It does not.	19	to limit competitive promotion."
20	Q. Okay. Do you have any reason to	20	Have I read that accurately?
21	believe that that is not an accurate report	21	A. Yes, ma'am.
22	about that study?	22	Q. And that was your conclusion?
23	MR. SNAPP: Object to the form.	23	A. Yes, ma'am.
24	A. I can't really say whether it's	24	Q. And finishing, I'm sorry, the next
25	accurate or not. There are contact reports	25	sentence, "This product has been shown to be as
	Page 151		Page 153
1	in the company report what the person on the	1	good as current therapy, but has not been shown
2	company side heard. I don't know what I said.	2	to have a significant advantage beyond reduction
3	BY MS. SINGER:	3	in frequency of dosing," correct?
4	Q. Although isn't this a report on a	4	A. That's what it says.
5	study that Purdue conducted?	5	Q. And that's what you wrote?
6	A. Yes.	6	A. I'm pretty sure that's what I wrote.
7	Q. Okay. So	7	It wasn't just me, that would have been me and
8	A. Since I don't remember the	8	Doug Kramer at that point. And I don't know if
9	conversation, and I don't, I can't say whether	9	this underwent another peer review, I just don't
10	his characterization of my response is accurate	10	remember, but it was two or three of us.
11	or inaccurate.	11	Q. Okay. And is this the same Doug
12	Q. Okay. So other than his	12	Kramer who was later at Purdue Pharma with you?
13	characterization of your response, do you have	13	A. Yes.
14	any reason to disbelieve the account of the	14	Q. And so when you say no significant
15	package insert testing study that's included	15	"has not been shown to have a significant
16	here?	16	advantage beyond reduction in frequency of
17	MR. SNAPP: Object to the form.	17	dosing," that means no reduction in adverse
18	A. I have no reason to doubt that.	18	effects, correct?
1		1	

19 MR. SNAPP: Object to the form. 20

A. I'd have to look at the integrated summary of safety to reach that conclusion. But it says what it says, it's not any better than conventional therapy.

BY MS. SINGER:

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Q. Okay. So when you say "competitive

Q. Okay. Do you know if this is a high

rate of non-compliance with the package insert?

these. Non-compliance with a package insert was

extremely common. Sometimes it was pernicious,

MR. SNAPP: Object to the form.

A. It's been too long since I looked at

19

20

21

22

23

24

25

BY MS. SINGER:

Page 154 Page 156 1 promotion," should take care not to engage in 1 this document, Dr. Wright? 2 competitive promotion, that means that, 2 A. It looks like an OxyContin package 3 3 insert, which version I don't know. consistent with your medical officer review or 4 4 the medical officer review which you co-authored Q. And if you could look at the middle 5 or participated in, Purdue could not represent column, and I have to get up close to see it --6 that OxyContin was more effective than other 6 sorry. Okay. We're actually going to go to 7 7 opioids, is that correct? Bates number 687, please. All right. If you 8 MR. SNAPP: Object to the form. 8 look in the middle column under the heading 9 9 A. Based on the document that I see, what "Drug Abuse and Dependence." 10 10 that kind of language usually means is a signal Do you see where I'm reading? 11 for DDMAC, for the division of drug advertising, 11 A. Yes, ma'am. 12 12 that since OxyContin was not tested against Q. Okay. And can you read aloud the last 13 13 other similar analgesics and shown to be better, sentence, "Delayed absorption"? 14 14 you can't make claims that it's better than MR. PETRILLO: Last sentence, first 15 15 other opioid analgesics. paragraph? 16 BY MS. SINGER: 16 MS. SINGER: Of that first paragraph, 17 17 Q. Okay. And would that include that it "Delayed absorption, as provided by OxyContin 18 was less likely to be abused than other opioid 18 tablets." 19 19 analgesics? A. "Delayed absorption, as provided by 20 20 MR. SNAPP: Object to the form. OxyContin tablets, is believed to reduce the 21 21 A. That's a -- you asked a difficult abuse liability of a drug." 22 question because it doesn't have a yes or no 22 BY MS. SINGER: 23 23 answer. At that time controlled-release dosage Q. Okay. Do you know who proposed that 24 forms which had a slower upsweep and onset were 24 language? 25 25 viewed to pose less risk of dependence or abuse A. I don't know. Page 155 Page 157 1 than immediate-release dosage forms. But that 1 Q. Okay. All right. Exhibit 17. 2 is, in general, a safety issue, and there is 2 (Whereupon, Purdue-Wright-17 was 3 3 great reluctance to allow promotion on safety marked for identification.) 4 unless there is a definitive proved safety 4 BY MS. SINGER: 5 advantage. 5 Q. Is SHC-4520, it's titled on the first 6 BY MS. SINGER: 6 page "8/2/95 Reder." 7 Q. Okay. And is there anything in your A. Mm-hmm. 8 memory or the medical officer report that 8 Q. Do you recognize that to be how Robert 9 9 indicates that OxyContin -- that Purdue had Reder spelled his name? 10 demonstrated that OxyContin had a proved safety 10 A. I thought there were two E's. 11 11 Q. Okay. All right. Do you see on 4521, advantage? 12 12 MR. SNAPP: Object to the form. the next page on the top it says "Reder 13 MR. PETRILLO: Objection. 13 Version"? 14 A. I'd have to look at the integrated 14 A. "Reder Version." 15 15 summary of safety before I could answer that. Q. Okay. Have you ever seen this version 16 16 BY MS. SINGER: of the package insert before? 17 17 Q. All right. We'll try to pull that A. I can't remember. 18 18 out. Q. Okay. And I just want you to turn the 19 19 A. Okay. page to 4522, please. Do you recognize that 20 20 Q. Okay. This is going to be taxing to handwriting? And you can page through the 21 read, but this is Exhibit 16. 21 document and see if the handwriting is familiar 22 (Whereupon, Purdue-Wright-16 was 22 to you. 23 23 marked for identification.) A. I don't know who that is. 24 BY MS. SINGER: 24 Q. Is it your handwriting? 25 25 Q. It's PKY183226682. Do you recognize A. No, it is not.

	Page 158		Page 160
1	Q. Okay. And so if we can turn to Bates	1	A. During my I'm having to reconstruct
2	number 4538, and can you see at line 580 there's	2	what I might have thought at the time, is that
3	some handwritten text on the right margin?	3	okay?
4	A. Mm-hmm.	4	BY MS. SINGER:
5	Q. And can you read, I know it's not	5	Q. Absolutely.
6	easy, can you decipher what is written there?	6	A. During my postdoctoral fellowship I
7	If you can't, I can do my best.	7	looked I was doing research and reviewed the
8	A. "Delayed new opioid activity as	8	literature on the development of tolerance to
9	provided by OxyContin tablets is believed to	9	opioids. Tolerance is a defensive reaction by
10	reduce the abuse liability of a drug."	10	the body to administration of opioids, and it
11	Q. Okay. Do you recall ever proposing	11	develops in everybody who takes an opioid, who
12	that language to Robert Reder?	12	has experienced an opioid effect, and it occurs
13	A. I don't remember specifically doing	13	at different speeds depending upon most likely
14	so, but I could have.	14	the area under the curve of the concentration
15	Q. Do you recall instances in which you	15	exposure time. The longer the drug is in and
16	proposed or dictated language to Dr. Reder?	16	the higher the level of the drug, the more
17	MR. SNAPP: Object to the form.	17	tolerance you get. Changing the pharmacokinetic
18	A. I recall instances in conferences with	18	profile from up, down, up, down, up, down to up,
19		19	
20	sponsors that I have proposed language. I don't	20	down, up, down could theoretically alter the
21	know what I proposed to Robert or not.	21	development of tolerance.
	BY MS. SINGER:		Q. And do you know in what direction it
22	Q. Or whether?	22	would alter the development of tolerance, if it
23	A. Or whether.	23	did?
24	Q. Okay. But you're certain this is not	24	MR. SNAPP: Object to the form.
25	your handwriting?	25	A. A longer apparent half-life would be
	Page 159		Page 161
	1 uge 13)		1 age 101
1	MR. PETRILLO: Form.	1	
1 2	_	1 2	likely to increase the development of tolerance, which is a good thing.
	MR. PETRILLO: Form.		likely to increase the development of tolerance,
2	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER:	2	likely to increase the development of tolerance, which is a good thing. BY MS. SINGER:
2 3	MR. PETRILLO: Form. A. No, that is not my handwriting.	2 3	likely to increase the development of tolerance, which is a good thing. BY MS. SINGER: Q. Okay. And when you talked about the
2 3 4	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to	2 3 4	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the
2 3 4 5	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.	2 3 4 5	likely to increase the development of tolerance, which is a good thing. BY MS. SINGER: Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think,
2 3 4 5 6	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14.	2 3 4 5 6	likely to increase the development of tolerance, which is a good thing. BY MS. SINGER: Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and
2 3 4 5 6 7	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.	2 3 4 5 6	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its
2 3 4 5 6 7 8	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.  Here you go.	2 3 4 5 6 7 8	likely to increase the development of tolerance, which is a good thing. BY MS. SINGER: Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and A. Plasma concentration, time. So its units are time and plasma concentration and
2 3 4 5 6 7 8 9	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.  Here you go.  A. And 055?	2 3 4 5 6 7 8	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.
2 3 4 5 6 7 8 9 10	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.  Here you go.  A. And 055?  BY MS. SINGER:	2 3 4 5 6 7 8 9 10	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate
2 3 4 5 6 7 8 9 10 11	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.  Here you go.  A. And 055?  BY MS. SINGER:  Q. 055. And can you read out loud the	2 3 4 5 6 7 8 9	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?
2 3 4 5 6 7 8 9 10 11 12	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.  Here you go.  A. And 055?  BY MS. SINGER:  Q. 055. And can you read out loud the first sentence?	2 3 4 5 6 7 8 9 10 11 12	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility	2 3 4 5 6 7 8 9 10 11 12 13	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose
2 3 4 5 6 7 8 9 10 11 12 13 14	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.  Here you go.  A. And 055?  BY MS. SINGER:  Q. 055. And can you read out loud the first sentence?  A. "There is a theoretical possibility that the slower fall and slightly higher trough	2 3 4 5 6 7 8 9 10 11 12 13 14	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose  A. The higher the plasma concentration.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	MR. PETRILLO: Form.  A. No, that is not my handwriting.  BY MS. SINGER:  Q. Okay. We're going to return to  Exhibit 14, or not. Yes. So if you can turn to  Bates number 055.  A. I'm having trouble finding 14.  MR. PETRILLO: Sorry. Let's see.  Here you go.  A. And 055?  BY MS. SINGER:  Q. 055. And can you read out loud the first sentence?  A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance	2 3 4 5 6 7 8 9 10 11 12 13 14 15	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose  A. The higher the plasma concentration.  Bigger doses should give a higher plasma
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose  A. The higher the plasma concentration.  Bigger doses should give a higher plasma concentration.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen in the database (see ISS), and the two daily	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose  A. The higher the plasma concentration.  Bigger doses should give a higher plasma concentration.  Q. And thus, yield more tolerance,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen in the database (see ISS), and the two daily troughs appear adequate based on the divisional	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose  A. The higher the plasma concentration.  Bigger doses should give a higher plasma concentration.  Q. And thus, yield more tolerance, correct?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen in the database (see ISS), and the two daily troughs appear adequate based on the divisional experience with 'trough-less' opioid dosage	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose  A. The higher the plasma concentration.  Bigger doses should give a higher plasma concentration.  Q. And thus, yield more tolerance, correct?  A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen in the database (see ISS), and the two daily troughs appear adequate based on the divisional experience with 'trough-less' opioid dosage forms such as Duragesic."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose  A. The higher the plasma concentration.  Bigger doses should give a higher plasma concentration.  Q. And thus, yield more tolerance, correct?  A. Yes.  MR. SNAPP: Object to the form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen in the database (see ISS), and the two daily troughs appear adequate based on the divisional experience with 'trough-less' opioid dosage forms such as Duragesic." Q. What was the basis of that theoretical	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose A. The higher the plasma concentration.  Bigger doses should give a higher plasma concentration.  Q. And thus, yield more tolerance, correct?  A. Yes.  MR. SNAPP: Object to the form.  BY MS. SINGER:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen in the database (see ISS), and the two daily troughs appear adequate based on the divisional experience with 'trough-less' opioid dosage forms such as Duragesic." Q. What was the basis of that theoretical possibility? What gave rise to that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	likely to increase the development of tolerance, which is a good thing. BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose A. The higher the plasma concentration. Bigger doses should give a higher plasma concentration. Q. And thus, yield more tolerance, correct?  A. Yes.  MR. SNAPP: Object to the form. BY MS. SINGER: Q. So Exhibit 18.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. PETRILLO: Form. A. No, that is not my handwriting. BY MS. SINGER: Q. Okay. We're going to return to Exhibit 14, or not. Yes. So if you can turn to Bates number 055. A. I'm having trouble finding 14. MR. PETRILLO: Sorry. Let's see. Here you go. A. And 055? BY MS. SINGER: Q. 055. And can you read out loud the first sentence? A. "There is a theoretical possibility that the slower fall and slightly higher trough might result in greater development of tolerance and/or withdrawal phenomenon. This was not seen in the database (see ISS), and the two daily troughs appear adequate based on the divisional experience with 'trough-less' opioid dosage forms such as Duragesic." Q. What was the basis of that theoretical	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	likely to increase the development of tolerance, which is a good thing.  BY MS. SINGER:  Q. Okay. And when you talked about the development of tolerance, you talked about the area under the curve as duration, I think, and  A. Plasma concentration, time. So its units are time and plasma concentration and time.  Q. And does plasma concentration relate to the dose?  A. Yes.  Q. Meaning the higher the dose A. The higher the plasma concentration.  Bigger doses should give a higher plasma concentration.  Q. And thus, yield more tolerance, correct?  A. Yes.  MR. SNAPP: Object to the form.  BY MS. SINGER:

Page 162 Page 164 1 BY MS. SINGER: start with Bates number 572, please. 2 Q. Which is PKY180715570. If you turn to 2 A. Yes. 3 the second page, 571, you'll see its title, 3 O. Okay. Do you know Dr. McCormick? 4 "OxyContin Meeting, April 23, 2001." And 4 A. She was my division director for a 5 certainly take a moment to look through it, but 5 brief period of time. I was her deputy in my 6 what I'd like you to tell me is whether this 6 last few months at the FDA. 7 7 seems to reflect the summary of a meeting Q. Okay. And so if you look down, so 8 between Purdue Pharma, the FDA -- sorry, Purdue third paragraph you see Dr. Pollock listed. Do 9 9 Pharma and the FDA. you remember, or did you know Dr. Pollock? 10 10 A. I don't remember ever meeting (Witness reviewing document.) 11 A. This appears to reflect minutes of a 11 Dr. Pollock. 12 12 meeting held between the FDA and Purdue Pharma. Q. Okay. At the bottom of that third 13 13 Q. Okay. And you're not listed as an paragraph with Dr. Pollock, it notes that 14 14 attendee at this meeting, correct? MS Contin prescribing had remained relatively 15 15 A. I am not listed as an attendee. constant, but OxyContin had increased ten fold. 16 Q. But if you look at the stamp on Bates 16 Was that -- do you know that to be 17 number 571, do you see a Received stamp? 17 true, or is it consistent with your 18 A. I do. 18 understanding of what happened to the sales of 19 Q. Does that indicate "Received May 14, 19 MS Contin and OxyContin? 20 2001, Curt Wright"? MR. SNAPP: Object to the form. 20 21 A. Yes, it does. 21 A. To be strictly accurate I'd have to 22 22 Q. And does that reflect a stamp that was look at the data. Sales of OxyContin did 23 23 put on correspondence when you received it? increase at some point during this period quite 24 A. I don't remember having correspondence 24 a bit. 25 25 stamped when I received it. BY MS. SINGER: Page 163 Page 165 1 Q. Could it be anyone else's? 1 Q. Okay. And then the next paragraph 2 A. I don't know who stamped it and why my talks about Dr. Hertz. Did you work with 3 name is on it. I don't really know. 3 Dr. Hertz? 4 Q. Okay. Do you go by Curt? 4 A. No. 5 A. No. I usually -- in the work Q. And do you know who she is? 6 environment I'm usually Curtis. My full name is A. She -- I think at this point she was 7 Curtis Wright. I don't remember ever seeing a on her way to becoming deputy director of the 8 stamp that looked like that before. 8 division. 9 9 Q. Okay. Do you remember receiving this O. Which division is that? 10 document? 10 A. The analgesic division. 11 11 A. No, I don't. Q. At FDA? 12 12 Q. Do you remember hearing about a A. At FDA. 13 meeting between Purdue and the FDA in April, 13 Q. Okay. And it says here "OxyContin is 14 14 2001 at which concerns about OxyContin were not necessarily the first opioid to be used and 15 15 it should not be an intermittent opioid." discussed? 16 16 MR. SNAPP: Object to the form. Do you see that sentence? 17 17 A. Yes. A. I don't -- I was not kept very well 18 18 informed, nor should I have been not being on Q. And is that consistent with what you 19 the OxyContin team, of what was happening with 19 were saying earlier about it being not 20 the FDA. The only time I found out about it was 20 necessarily appropriate for all patients in the 21 when somebody asked me some question. 21 first instance? 22 22 BY MS. SINGER: MR. SNAPP: Object to the form. 23 23 Q. Okay. Okay. Let's turn, and we'll A. Since it's somebody else's comment I

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talk about this from your experience, but --

sorry, too many pages. All right. If we can

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can just say whether I agree with it or not. I

agree with "OxyContin is not necessarily the

Page 166 Page 168 first opioid to be used and it should not be 1 Do you see where that is? 2 2 used as an intermittent opioid." A. Hang on a second. What paragraph is 3 3 BY MS. SINGER: that. 4 4 Q. Okay. All right. And then if you go Q. It's the second full paragraph that 5 starts "Tom Abrams interjected," and it's the down to the last paragraph, "She would also like 6 to see educational efforts increased including 6 last line of that paragraph. 7 7 A. Yes, I see it. possibly a Medguide for patients on the risks of 8 overdose and the abuse of opioids as well as 8 Q. Okay. Do you know if Purdue undertook 9 9 bringing in a nationwide market research firm to risks for use by others than whom it was 10 10 prescribed." conduct this research? 11 Were you aware that that 11 A. I don't know. I mean, I don't know 12 12 recommendation was made to Purdue? either way. 13 13 A. If I was, I certainly don't remember Q. Okay. Now, you talked earlier about 14 it now. 14 the surveillance that Purdue did, RADARS and 15 15 Q. Okay. And sitting here, do you agree efforts like that. Are you familiar with the 16 that that was a step that Purdue should have 16 Top 100 Counties initiative at Purdue? 17 17 considered --A. No. 18 18 MR. SNAPP: Object to the form. Q. And did you ever become aware of Maine 19 BY MS. SINGER: 19 as a hotspot, obviously not a county, but for 20 20 opioid abuse and diversion? Q. -- in 2001? 21 21 MR. SNAPP: Object to the form. MR. PETRILLO: Object to the form. 22 A. If it's recommended by a senior 22 A. Okay. I became aware that upstate 23 23 physician in the FDA, you certainly should Maine had a significant abuse and division 24 consider it. 24 problem. 25 25 BY MS. SINGER: BY MS. SINGER: Page 167 Page 169 Q. And given your knowledge of abuse and 1 1 Q. Do you remember when you became aware 2 2 of that? adverse effects from the abuse of an addiction 3 3 to OxyContin, does that also strike you as a A. I'm not sure. 4 prudent recommendation? 4 Q. Okay. I'll give you all these. So 5 MR. SNAPP: Object to the form. 5 this is Exhibit 19. 6 A. It's amazing -- it's very difficult to 6 (Whereupon, Purdue-Wright-19 was 7 7 be -- to object to a well written, useful med marked for identification.) 8 guide. When you initiate a med guide is really 8 BY MS. SINGER: 9 9 an agency decision. I don't know of -- well, Q. So it doesn't have a Bates number, 10 I'm not familiar with writing a -- going through 10 it's "Prescription Drugs. OxyContin Abuse and 11 11 the expense of writing a med guide voluntarily. Diversion and Efforts to Address the Problem," 12 But a med guide is one of the first things the 12 dated December, 2003 by the GAO. 13 13 agency pulls out of its toolbox when it Do you recognize this document? 14 perceives an emerging problem. 14 A. I read it -- I recognize that I read 15 15 BY MS. SINGER: something like this at the time. 16 16 Q. And then if you look at Bates number Q. Okay. And that would have been back 17 17 574, Paragraph 3, do you recognize the name Tom somewhere around December, 2003? 18 18 Abrams? A. 2003. 19 19 A. Not at this time. Q. Okay. And if you could turn to Page 10 of the report, please. 20 Q. And it indicates here, the bottom of 20 21 that paragraph, "He also would like to see 21 A. Okay. 22 nationwide market research from healthcare 22 Q. Do you see in the first full paragraph 23 practitioners to determine what the message is 23 on the report "After learning about the initial 24 the doctors are getting from our promotional 24 reports"? 25 25 efforts." A. I see that paragraph.

	Page 170		Page 172
1	Q. Do you mind reading that out loud,	1	number 579. Do you see the first slide,
2	please?	2	"Preparation: Maine Strike Force"?
3	A. "After learning about the initial	3	A. Mm-hmm.
4	reports of abuse and diversion of OxyContin in	4	Q. And under the third indented bullet of
5	Maine in 2000, Purdue formed a response team	5	internal personnel, do you see your name?
6	made up of its top executives and physicians to	6	A. Yes, I do.
7	initiate meetings with federal and state	7	Q. Okay. And does that refresh your
8	officials in Maine to gain an understanding of	8	recollection about anything you might have done
9	the scope of the problem and to devise	9	in connection with the Maine Strike Force?
10	strategies for preventing abuse and diversion."	10	A. No, because I don't think I did
11	Q. You can read one more sentence,	11	anything. I mean, I can't identify anything
12	please.	12	with respect to the Maine Strike Force.
13	A. "After these meetings, Purdue	13	Q. Okay. And I just want to turn you
14	distributed brochures to healthcare	14	back to the first page. I'm sorry, let's start
15	professionals that described several steps that	15	actually on the second page which is Bates
16	could be taken to prevent prescription drug	16	number 574. Under "Today's Situation" it
17	abuse and diversion."	17	describes "Increased media exposure of diversion
18	Q. And were you familiar with that effort	18	and abuse of OxyContin in Maine." That's
19	at Purdue Pharma?	19	something you recall, correct?
20	A. I don't know if I was familiar at the	20	A. Yes.
21	time. I don't remember it.	21	Q. And "Numerous physician inquiries
22	Q. Okay. Do you recall if you were	22	about Purdue's plans to address abuse issue."
23	involved in any effort like that?	23	Was that something that you remember being
24	A. I could have been. I don't I	24	involved in or hearing about at Purdue?
25	honestly don't remember.	25	A. That would have gone someplace other
	•		71. That would have gone somephace other
	Page 171		Page 173
1	Q. Okay.	1	than me. That wouldn't have gone to my group.
2	(Whereupon, Purdue-Wright-20 was	2	Q. Okay. Do you remember hearing about
3	marked for identification.)	3	it?
4	BY MS. SINGER:	4	A. We knew about the I knew about the
5	Q. Exhibit 20 is PKY180277573, and it's a	5	cases in Maine, and I knew about Maine's concern
6	PowerPoint titled "Protecting Patients' Rights	6	about the cases. I don't know I don't know
7	to Proper Pain Management - New England	7	how many physician inquiries we got or what the
8	Initiative."	8	physicians were saying.
9	Have you seen this document before,	9	Q. Okay. And what about the last bullet,
10	this presentation?	10	"Evidence of patient concern and reticence to
11	A. I don't think so.	11	use drug," were you aware of that?
12	Q. Okay. And do you know who Robin Hogen	12	A. I have no idea about that.
13	is?	13	Q. Okay. All right. And moving to the
14	A. I don't know his exact title, but I	14	second slide on this page under the heading "How
15	knew where his office was in the building.	15	Did We Get Here?", did you hear that the US
16	Q. Okay. And this is he's someone you	16	attorneys sent a letter to healthcare providers
17	interacted with or worked with at Purdue?	17	in Maine warning of OxyContin abuse?
18	A. On a limited number of times.	18	A. I don't know about that.
19	Q. Okay. And do you know if he was a	19	Q. Okay. And then just turning back to
20	doctor or a scientist?	20	the first slide, actually the second slide on
21	A. He was a I don't know what his	21	the first page, 573, do you see the slide "Goal
			•

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much as I knew.

executive in the company, and that's about as

Q. Okay. So if you could turn to Bates

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A. (Nodding in the affirmative).

Q. And can you read aloud what's listed

there as goals -- as a goal and objective for

	girry contractional Subject to		
	Page 174		Page 176
1	Purdue Pharma?	1	Q. Okay. I wanted to turn your to slide
2	MR. SNAPP: Object to the form.	2	eight. It's not numbered, but it is the slide
3	A. "Goals and Objectives.	3	that's titled "Abuse and Addiction." And in
4	"Sustain and increase OxyContin	4	this slide there's a distinction between
5	prescriptions.	5	addiction liability and abuse liability.
6	"Increase proactive treatment of pain.	6	Addiction liability is "The risk that an
7	"Position OxyContin as safe and	7	individual patient, using the drug as directed,
8	effective therapy."	8	will develop symptoms of addiction to the drug."
9	And "Diffuse concerns about	9	Is that an accurate statement or an
10	OxyContin/opioids stemming from high profile	10	accurate description of addiction liability?
11	news coverage of abuse."	11	A. Actually addiction liability, looking
12	Q. And do you remember discussions about	12	at it today, is not a recognized term of art in
13	efforts to accomplish those goals and	13	this area.
14	objectives?	14	Q. Was it a term of art then?
15	MR. SNAPP: Object to the form.	15	A. It's what I wrote then, I think. What
16	A. Those weren't the discussions we were	16	I was trying to do in today's terms would be to
17	having.	17	differentiate between misuse, abuse and
18	BY MS. SINGER:	18	diversion, and iatrogenic addiction.
19	Q. Okay.	19	Q. Okay. So what would you change, if
20	A. I mean, not in my group.	20	anything, about the description of addiction?
21	Q. Okay. And you don't recall	21	MR. SNAPP: Object to the form.
22	discussions with Robin Hogen's group about that?	22	A. I would probably add "properly managed
23	A. No, no, no, not at all.	23	individual patient."
24	Q. You're getting a reprieve from one	24	BY MS. SINGER:
25	document.	25	Q. Okay. So the risk that properly
	D 175	-	
- 1			
	Page 175		Page 177
1	Okay. This document we're about to	1	managed individual patients using the drug as
2	Okay. This document we're about to mark was produced natively under the Bates	2	managed individual patients using the drug as directed?
2 3	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21.	2 3	managed individual patients using the drug as directed?  A. Will develop addiction to the drug.
2 3 4	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21. (Whereupon, Purdue-Wright-21 was	2 3 4	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse
2 3 4 5	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21. (Whereupon, Purdue-Wright-21 was marked for identification.)	2 3 4 5	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other
2 3 4 5 6	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21. (Whereupon, Purdue-Wright-21 was marked for identification.) MS. SINGER: Can I take one of those	2 3 4 5 6	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and
2 3 4 5 6 7	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21. (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.	2 3 4 5 6 7	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views
2 3 4 5 6 7 8	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21. (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.  BY MS. SINGER:	2 3 4 5 6 7 8	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views on what abuse liability of a drug is?
2 3 4 5 6 7 8	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21.  (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.  BY MS. SINGER:  Q. And if you can turn to the first	2 3 4 5 6 7 8	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views on what abuse liability of a drug is?  A. Well, that's the risk of misuse,
2 3 4 5 6 7 8 9	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21.  (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.  BY MS. SINGER:  Q. And if you can turn to the first colored page. By all means, take your time to	2 3 4 5 6 7 8 9	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views on what abuse liability of a drug is?  A. Well, that's the risk of misuse, abuse, and diversion. In this slide I was
2 3 4 5 6 7 8 9 10	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21.  (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.  BY MS. SINGER:  Q. And if you can turn to the first colored page. By all means, take your time to look through it.	2 3 4 5 6 7 8 9 10	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views on what abuse liability of a drug is?  A. Well, that's the risk of misuse, abuse, and diversion. In this slide I was trying to separate two conflated ideas, that
2 3 4 5 6 7 8 9 10 11	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21.  (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.  BY MS. SINGER:  Q. And if you can turn to the first colored page. By all means, take your time to look through it.  (Witness reviewing document.)	2 3 4 5 6 7 8 9 10 11	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views on what abuse liability of a drug is?  A. Well, that's the risk of misuse, abuse, and diversion. In this slide I was trying to separate two conflated ideas, that there were two domains in which you worried
2 3 4 5 6 7 8 9 10 11 12	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21.  (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.  BY MS. SINGER:  Q. And if you can turn to the first colored page. By all means, take your time to look through it.  (Witness reviewing document.)  Q. Tell me whenever you're ready to talk	2 3 4 5 6 7 8 9 10 11 12	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views on what abuse liability of a drug is?  A. Well, that's the risk of misuse, abuse, and diversion. In this slide I was trying to separate two conflated ideas, that there were two domains in which you worried about abuse of a drug, iatrogenic addiction,
2 3 4 5 6 7 8 9 10 11 12 13 14	Okay. This document we're about to mark was produced natively under the Bates number PPLPC013000068011. It's Exhibit 21.  (Whereupon, Purdue-Wright-21 was marked for identification.)  MS. SINGER: Can I take one of those back? I'm sorry.  BY MS. SINGER:  Q. And if you can turn to the first colored page. By all means, take your time to look through it.  (Witness reviewing document.)  Q. Tell me whenever you're ready to talk about it.	2 3 4 5 6 7 8 9 10 11 12 13	managed individual patients using the drug as directed?  A. Will develop addiction to the drug. Q. Okay. And let's turn to the abuse liability. "The risk that individuals other than legitimate patients will misuse, abuse, and divert the drug." Does that reflect your views on what abuse liability of a drug is?  A. Well, that's the risk of misuse, abuse, and diversion. In this slide I was trying to separate two conflated ideas, that there were two domains in which you worried about abuse of a drug, iatrogenic addiction, misuse, abuse and diversion.
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that a properly managed -- properly selected and 2 managed patient who has an appropriate condition 3 who receives treatment with the drug becomes 4 addicted to the drug.

Q. And you have defined different domains, but an individual who becomes addicted to an opioid can also abuse an opioid, correct?

MR. SNAPP: Object to the form.

A. Everybody who has become addicted is abusing an opioid. Everybody who is abusing an opioid is not necessarily addicted. People can engage in misuse and diversion who aren't abusers or addicted, they're selling them. And what everybody struggles with is that these terms are all conflated and mean different things to different people.

It looks like in this presentation I was trying to say there's two things you have to worry about and both are important, one is the iatrogenic addiction and the other is misuse, abuse and diversion.

BY MS. SINGER:

Q. Okay. So let's turn to slide 13, which is titled "The Goal." Do you recall what you're talking about in this slide, what the

population other than the individual patient with the individual condition, if you integrate

3 pharmacoepidemiology into your thinking, you'll

be more successful.

(Whereupon, Purdue-Wright-22 was marked for identification.)

BY MS. SINGER:

Q. All right. Exhibit 22 is PDD8901212709 titled "Overall Medical Strategy for Purdue Opioid Products (Abuse and Diversion Resistance)."

Do you recognize this document?

- A. I recognize it. I don't remember where I gave it, but I think it's -- I think it's a -- help me -- presentation I gave.
- Q. Okay. And does the date March 1st through 2nd, 2005 seem about right? No reason -- or no reason to believe it's not right?
- A. I don't know whether it's right or not, but it's what's written on the page.
- Q. Okay. If you can turn to 2723. The Bates numbers are in the bottom corner.

MR. SNAPP: Can you give him a moment to look through the entire document, please?

MS. SINGER: If he asks, I'm happy --

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1 goal is?

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A. I do not remember independently. Reading this slide, I can conjecture.

Q. And what is your conjecture? MR. SNAPP: Object to the form.

A. Back in 1990, 1995, 1985, back in that period, abuse of a pharmaceutical was considered to be a criminal justice problem. It was a problem for the cops. That, by definition, if a product was being abused, misused or diverted it was not being used as directed, and that did not affect the perceived safety profile of the drug.

By this point in time, and certainly going forward, what happens to the rest of society is viewed as an important part of the safety profile of the drug, that you can't view it as a criminal justice problem. That's where I was going with this.

BY MS. SINGER:

- Q. Okay. In the third bullet, "Companies that make an advantage of the new situation will find a new market opportunity and thereby win," what are you referring to there?
- A. If you recognize that it is important to consider the safety of the rest of the

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MR. SNAPP: If he needs --MS. SINGER: Excuse me?

MR. SNAPP: If he wants time to look through the entire document, may he take --BY MS. SINGER:

Q. So, Dr. Wright, let me just say so we don't have to have these interactions, if you ever need more time for a document, just ask, and you're welcome to take whatever time you need.

MR. SNAPP: Thank you.

A. I'm just familiarizing myself with what I said in this particular presentation. I gave dozens.

BY MS. SINGER:

16 O. Sure. Of course. 17 (Witness reviewing document.) 18

A. Okay.

- Q. Okay. And if you can turn now to Bates number 723, which is titled "The Abuse Problem."
- A. I'm having problems finding Bates number 723.
- Q. If you turn it sideways, that might help orient it like it's not a PowerPoint. And

Page 182 Page 184 1 it's going to be in the back third. A. It reflects my views -- in 2005 I 2 A. Yes. would have agreed with the statement because I 3 Q. Got it? 3 wrote it that "abuse appears proportional to the 4 Okay. First of all, before getting to potency and amount of the opioid prescribed." 5 the particulars, I know you mentioned DAWN 5 Q. And do you still agree with that 6 before, but can you describe what DAWN ED 6 statement? 7 mentions are? 7 A. I still agree with that statement. 8 8 A. The federal government and in Q. Okay. And the relationship between --9 9 conjunction with a number of medical never mind. Withdrawn. 10 10 institutions runs a continuing and ongoing A. May I also make sure that you 11 survey where nurses are sent in to go through 11 correctly interpret that graph that you looked 12 12 emergency room records and abstract mentions at? 13 13 involving drug abuse, those are ED mentions. Q. Sure. 14 14 They are not representing individual cases A. It doesn't matter what the opioid is. 15 15 because a person could have two drugs in their It didn't matter which one it was. They all 16 mention because they were abusing two drugs. 16 fell on the same line. 17 Those are then statistically compiled and made 17 Q. Meaning the more drug, the greater the 18 18 available to the rest of the scientific potency, the more abuse? 19 19 community. A. All of the Schedule II strong opioids, 20 Q. Okay. And what do DAWN ED mentions 20 all of the strong opioids have about the -- have 21 21 serve to indicate to you? the same relationship at about the same 22 A. They're a surrogate of abuse of a drug 22 magnitude. 23 23 in the community. Q. I know you said you gave lots of 24 Q. Okay. And I'm never going to say it, 24 presentations. I don't think we'll take you 25 on the bottom axis, equianalgesic doses? 25 through all of them, but this is Exhibit 23. Page 183 Page 185 A. Yes. 1 (Whereupon, Purdue-Wright-23 was 1 2 Q. Did I say that right? 2 marked for identification.) 3 A. Equianalgesic doses. 3 BY MS. SINGER: 4 Q. What does that represent? 4 Q. It's also produced natively, 5 A. People confuse potency and strength. PPLPC013000094578. It's titled 6 Potency is how strong it is; strength is how "Tamper-Resistance (What it is, What it isn't, 7 7 much there is of it. When you prescribe a drug What we need)." 8 there could be huge differences in the potency 8 When you've had a chance to go through 9 9 of the drug and, thus, in the dose that's used. it, can you tell me if you recognize this 10 So a dose of fentanyl could be 300 micrograms 10 presentation? 11 or -- yeah, micrograms, a dose of morphine might 11 A. I recognize it as one of the Opioid X 12 12 be 5 milligrams, a dose of Codeine could be presentations. I don't remember -- once again, 13 60 milligrams. When you want to compare the two 13 I don't remember which one of them it was. 14 you can't just say, well, here's a milligram of 14 Q. Okay. So you don't remember who the 15 15 fentanyl, because that's a huge amount of audience was for this? 16 fentanyl. So you have to take and make the 16 A. Not -- I don't remember what the 17 17 equianalgesic doses, the doses adjusted to audience was. But this is long enough and 18 18 morphine equivalence, so that you're looking at formal enough so that it was likely presenting 19 19 apples and apples instead of apples and oranges. outside of the group itself to someone else in 20 20 Q. Okay. Next to this chart, can you the company. 21 read what's written there? 21 Q. All right. Let's turn to slide four. 22 22 So again, these aren't numbered because it's A. "Abuse appears proportionate to the 23 23 potency and amount of the opioid prescribed." native, but it is the slide that has "NHS Drug 24 Q. Is that your view as of 2005? 24 Abuse." 25 25 MR. SNAPP: Object to the form. And does that slide show the same

Page 186 1 relationship that we were just talking about? don't think it's a medical phrase. But I think 2 MR. SNAPP: Object to the form. it accurately reflects what someone who is 3 3 active alcohol or drug-dependent feels. By the A. No. 4 4 time their addiction has become severe, they're BY MS. SINGER: 5 Q. Is it different? not taking the drug to get high or get euphoric 6 MR. SNAPP: Object to the form. or feel pleasure, they're taking the drug to 7 A. This slide is a slide of year by year. feel normal, they're taking the drug to 8 It's a government slide, I didn't -- we didn't function. They're hurting. 9 BY MS. SINGER: produce this data, and the government had 10 finally decided on new non-medical use as their 10 Q. And it's true they're -- well, you 11 term. It meant that it was non-medical use and 11 said it. 12 12 it was new. They didn't use abuse or addiction And then the last bullet there, 13 or diversion, they used new non-medical use as 13 "Accidental and intentional ODs are expected." 14 14 their standard. And this was, I think, the A. Yes. 15 15 National Center for Health Statistics, but I'm Q. You also agree with that statement 16 not -- might be National Health Service, I'm not 16 still? 17 sure what the acronym is at this point, it's 17 A. Yes. 18 18 been too long. MR. SNAPP: Object to the form. 19 19 BY MS. SINGER: But what this shows is the number of 20 20 cases that NHS calculated from their statistics Q. So let's turn to the slide that's 21 21 titled "Where is the problem?" Why don't you for per year from 1965 to 2000. 22 22 read this one, please, if you will. BY MS. SINGER: 23 23 Q. Okay. And it shows that the A. "Where is the problem? 24 trajectory increases over time, and particularly 24 "There are 1 to 2 million opioid 25 25 steeply after the mid 1990s, correct? addicts in the US. Page 187 Page 189 MR. SNAPP: Object to the form. "There are 7 to 9 million opioid 1 1 2 2 A. That is correct. abusers. 3 3 BY MS. SINGER: "There are 10 million or more 4 Q. So turning to "Risk Assessment," you 4 experimenters. indicate there that "The increase in opioid 5 5 "Addicts prefer 'optimized' opioids. 6 usage...is a major advance in pain management, 6 "Addicts can get opioid as methadone." 7 but has occurred in a period with a significant 7 And there are now others. 8 increase in prescription opioid abuse." And you 8 "Most drug abuse casualties are among 9 acknowledge this is a very big problem. I take 9 the abusers who surprise 70 to 80 percent of the 10 10 it that's still your view? purchasers. 11 11 A. This slide --"Most of the diverted drug goes to the 12 12 addicts, who are the frequent, high volume MR. SNAPP: Object to the form. 13 users." 13 A. -- says it's a problem, it's a very 14 big problem. I agree with that. 14 Q. Again, does this reflect your views as 15 BY MS. SINGER: 15 of the time you wrote this PowerPoint? 16 Q. Too much paper. Forgive me. 16 A. Yes. 17 All right. If you turn to the slide 17 Q. And now? that is titled "Addicts." If you can look at 18 18 MR. SNAPP: Object to the form. 19 19 the last bullet, or the last two bullets, A. I'm not sure that -- I've been out of 20 20 "Taking drug to feel normal is part of it too long. I don't know if the numbers are 21 addiction." 21 still right. 22 22 Is that an accurate statement? BY MS. SINGER: 23 MR. SNAPP: Object to the form. 23 Q. Okay. For the drug abuse casualties 24 A. The statement "taking drug to feel 24 here in the statistics about abusers, again I

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normal is part of addiction" is colloquial. I

know you talked earlier about two domains, but

Page 190 Page 192 is it fair to say that people who begin as reduced abuse profile? 2 2 addicts are also abusers, people -- I'm sorry, MR. SNAPP: Object to the form. 3 began as patients can become addicts and 3 MR. PETRILLO: Object. 4 4 abusers? A. The whole presentation was part of the 5 5 Opioid X portfolio which was a huge program that MR. SNAPP: Object to the form. 6 A. People who become -- people who are 6 Purdue mounted to try to find out how you would 7 patients can become abusers. People who are make a less abusable, less divertable product. 8 patients can become addicts. People who are not It was not as simple as I thought. And this 9 patients can become abusers. People who are not proposal looks like it was presented to an 10 10 patients can become addicts. And there's a wide audience that I was trying to make it very clear 11 variation in vulnerability, and this is a 11 to them that you need to do this, you need to do 12 12 this for a new product, the world has changed. problem that affects the entire population. 13 13 BY MS. SINGER: BY MS. SINGER: 14 14 Q. All right. If you can turn to the Q. Okay. 15 15 last slide titled "Life-Cycle Management." So MR. PETRILLO: Is now a good time for 16 the first intended line, "If targeted for large 16 a short break before you go to the next 17 17 document? FP/GP markets." Can you explain what that is? 18 18 A. If a drug is going to be used in a MS. SINGER: Yes, that's fine. And 19 large patient population it needs to have a 19 I'm in the -- let's go off the record. 20 20 THE VIDEOGRAPHER: We are now going reduced risk, abuse risk profile. 21 21 Q. And what does FP stand for? off the record, and the time is 2:42 p.m. 22 22 A. Family practitioner/general (Whereupon, a recess was taken.) 23 23 practitioner. THE VIDEOGRAPHER: We are now going 24 Q. Got it. 24 back on the record, and the time is 2:55 p.m. 25 25 And the various bullets here, if Page 191 Page 193 1 targeting large family practitioners or general 1 (Whereupon, Purdue-Wright-24 was 2 practitioner, large outpatient sales, emerging 2 marked for identification.) 3 abuse trends continue upward, all of these 3 MS. SINGER: All right. Exhibit 24 is 4 PKY180816855, another Sponsor Meeting Minutes. listed here are reasons for moving to reduced 4 5 abuse risk drugs, correct? 5 BY MS. SINGER: 6 A. That is correct, ma'am. 6 Q. And, Dr. Wright, please take your time 7 7 and take a look, let me know if you recognize Q. Okay. And some of these relate --8 8 withdrawn. this document. 9 9 So one of -- your last bullet here (Witness reviewing document.) 10 talks about avoiding restrictions on marketing. 10 Q. So, Dr. Wright, do you recognize this 11 11 Explain what you mean by that. document? 12 12 A. If the FDA is doing its job and a A. Yes, I do. 13 13 Q. And what do you recognize it to be? product has too high an abuse risk for the 14 population that it's going into, the FDA will 14 A. I recognize it to be more minutes from 15 15 have to step in and restrict marketing. the sponsor of a meeting between the FDA and the 16 16 Q. And what about for competitive company. 17 17 advantage and differentiation, what do you mean Q. Okay. And the meeting took place May 18 18 14th, 1997, does that seem accurate? 19 19 A. If I was a practitioner and I had a A. That seems accurate. 20 choice between a product that I credibly 20 Q. And you were the chair of this 21 believed was tamper-resistant or had a reduced 21 meeting, correct? abuse potential, and one that didn't, I'd pick 22 22 A. I think it means I was senior at the 23 the one that did. 23 meeting, but yes. 24 Q. Okay. And all of these still strike 24 Q. And you were at the FDA at this point, 25 you as the reasons, yes, among the reasons for 25 correct?

	птζ	Jilly Collindelicial - Subject to	O	Further Confidentiality Review
		Page 194		Page 196
	1	A. I believe so.	1	What's parenteral abuse?
	2	Q. Okay. And do you recall what this	2	A. Parenteral is medical for injecting.
	3	meeting related to?	3	Q. Okay. For this but "for this
	4	A. I don't actually remember this meeting	4	product there is a greater potential for oral
	5	being this meeting as I remember the meeting,	5	ne use man parenterar ne use.
	6	but the minutes are quite clear.	6	The That's what it says.
	7	Q. Okay.	7	Q. And is that accurate?
	8	A. This would be the HXA, or the HX	8	11. Toeneve so.
	9	was it HXA or HX?	9	Q. Okay. This you also maleute I think
	10	(Witness reviewing document.)	10	the router built from the cottom that
	11	Q. I don't think you need to refer to it	11	The spensor should demonstrate that the drug
		by the product name.	12	communion will not cause ususe of dependence.
	13	A. Okay.	13	Bo you see that.
	14	Q. But is it correct to say	14	The Tubil Child Will Hall Was His
	15	A. This was a hydrocodone/naloxone	15	recommendation, out that was the 1211s
		combination.	16	Tee of mile means of the second of the secon
	17	Q. Okay. And it's a meeting not just	17	Q. Only. The that The sponsor needs to
		between Purdue and the FDA, right?	18	demonstrate net benefit of the combination
	19	A. It included Frank Sapienza and	19	product to the paone.
		Gretchen, who I think I remember, but Frank for	20	11. 105.
	21 22	sure from the DEA.	22	Q. The that The sponsor shan
		Q. And also someone from NIDA, which	23	demonstrate in Chinear and Freemitear stadies
	24	stands for?	24	that the addition of I talonone in this drag
	25	<ul><li>A. National Institutes on Drug Abuse.</li><li>Q. Okay. And according to the minutes,</li></ul>	25	product will deter deale in som oproid harve
Ĺ				
		Page 195		Page 197
		and to the best of your recollection, Purdue had	1	witt. Brand 1. Object to the form. It
		asked for this meeting to discuss this reduced	2	says addition, and I timing you said addiction.
		abuse liability hydrocodone product, correct?	3	Thi safe you want a clear record. Tou said
	4	A. Yes.	4	addretion.
	5	Q. And did Purdue have a request for how	5	MD. DITTOLIK. I build uddition.
	6 7	this drug should be scheduled?		. A A 11 , 1 ',
		MD CNIADD. Object to the forms		A. Allow me to reread it.
		MR. SNAPP: Object to the form.	7	MR. SNAPP: I want to make sure the
	8	A. What it says in the minutes is that	8	MR. SNAPP: I want to make sure the record is clear.
	8 9	A. What it says in the minutes is that the sponsor believes that the drug product	8	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.
	8 9 10	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV.	2 9 10	MR. SNAPP: I want to make sure the record is clear. A. These terms get confused. BY MS. SINGER:
	8 9 10 11	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER:	10	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER: Q. Particularly with typos.
	8 9 10 11	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug?	10 11 12	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in
	8 9 10 11 12	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the	10 11 12 13	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in both clinical and preclinical studies that the
	8 9 10 11 12 13	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and	10 11 12 13	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER: Q. Particularly with typos. A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will
	8 9 10 11 12 13 14	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and potential of the drugs in the schedule. My	10 11 12 13	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will deter abuse in both opioid naive patients and
	8 9 10 11 12 13 14 15	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and potential of the drugs in the schedule. My memory, which may be correct, was that at this	10 11 12 13 14 15	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will deter abuse in both opioid naive patients and opioid dependent patients." That's what the
	8 9 10 11 12 13 14 15 16	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and potential of the drugs in the schedule. My memory, which may be correct, was that at this time the hydrocodone, APAP/hydrocodone, aspirin,	10 11 12 13 14 15	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will deter abuse in both opioid naive patients and opioid dependent patients." That's what the minutes say.
	8 9 10 11 12 13 14 15 16 17 18	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and potential of the drugs in the schedule. My memory, which may be correct, was that at this time the hydrocodone, APAP/hydrocodone, aspirin, hydrocodone/NSAID combinations were in Schedule	10 11 12 13 14 15 16	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will deter abuse in both opioid naive patients and opioid dependent patients." That's what the minutes say.  Q. Okay. And those seem to be accurate
	8 9 10 11 12 13 14 15 16 17 18	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and potential of the drugs in the schedule. My memory, which may be correct, was that at this time the hydrocodone, APAP/hydrocodone, aspirin, hydrocodone/NSAID combinations were in Schedule IV. Hydrocodone itself was in either III or II.	10 11 12 13 14 15 16 17	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will deter abuse in both opioid naive patients and opioid dependent patients." That's what the minutes say.  Q. Okay. And those seem to be accurate reflections of what was conveyed to Purdue at
	8 9 10 11 12 13 14 15 16 17 18 19 20	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and potential of the drugs in the schedule. My memory, which may be correct, was that at this time the hydrocodone, APAP/hydrocodone, aspirin, hydrocodone/NSAID combinations were in Schedule IV. Hydrocodone itself was in either III or II. Q. Okay. Then if you look down the page	10 11 12 13 14 15 16 17 18	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER:  Q. Particularly with typos.  A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will deter abuse in both opioid naive patients and opioid dependent patients." That's what the minutes say.  Q. Okay. And those seem to be accurate reflections of what was conveyed to Purdue at that meeting, correct?
	8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. What it says in the minutes is that the sponsor believes that the drug product should be Schedule IV. BY MS. SINGER: Q. And what is a Schedule IV drug? A. Okay. A Schedule IV drug has the second from the bottom abuse liability and potential of the drugs in the schedule. My memory, which may be correct, was that at this time the hydrocodone, APAP/hydrocodone, aspirin, hydrocodone/NSAID combinations were in Schedule IV. Hydrocodone itself was in either III or II.	10 11 12 13 14 15 16 17 18 19	MR. SNAPP: I want to make sure the record is clear.  A. These terms get confused.  BY MS. SINGER: Q. Particularly with typos. A. "The sponsor should demonstrate in both clinical and preclinical studies that the addition of naloxone in this drug product will deter abuse in both opioid naive patients and opioid dependent patients." That's what the minutes say. Q. Okay. And those seem to be accurate reflections of what was conveyed to Purdue at that meeting, correct?  MR. SNAPP: Object to the form.

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indicating that I think it's meant to be

"addition of naloxone to an oral product may

reduce the likelihood of parenteral abuse."

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Q. And then if you turn to Bates number

857, the fourth bullet point notes "Dr. Wright

BY MS. SINGER:

Page 198 1 noted that hydrocodone abuse is primarily oral." 1 of less abuse potential that seems to have 2 2 taught your attention, is that -- or that's the Again, does that reflect your 3 3 understanding of hydrocodone abuse? focus of your comment, is that correct? 4 4 A. The hydrocodone products on the market MR. SNAPP: Object to the form. 5 5 at that time were not injectable. They could --A. I think the point I'm trying to make 6 6 is do not hold false expectation of being able they contained large amounts of Tylenol or 7 another aspirin or another NSAID, and so abuse to make less abusable claims because DEA and 8 of those products was mostly oral, DDMAC will have strong feelings on the subject. 9 9 immediate-release oral. BY MS. SINGER: 10 10 Q. So at the end of that bullet point it Q. Okay. And isn't there some risk that 11 reports here that "As the data suggest the abuse 11 in advertising the product as having less abuse 12 12 is almost exclusively oral, what we would need potential that you will prompt even greater 13 13 to see with this product is that the oral abuse prescribing, that doctors will lose caution 14 14 liability, particularly in the opioid abuser, is about the product? 15 15 reduced." MR. SNAPP: Object to the form. 16 Does that seem sensible to you? 16 BY MS. SINGER: 17 17 A. That seems sensible. Q. Is that fair? 18 18 MR. SNAPP: Object to the form. Q. And then the last bullet point, 19 "Dr. Wright recommended that the sponsor work 19 A. It depends on what you're doing. 20 with DEA and DDMAC in the advertising of the 20 Because if you're prescribing in context, and 21 21 'less abuse potential' than competitor's you say this is a Schedule II narcotic that has 22 products." 22 high abuse potential, any claims you make about 23 23 Do you see that point? lowered abuse potential will be ignored. But if 24 A. I see that point. 24 you have a big banner that says less abuse 25 25 Q. Does that also seem sensible to you? potential, and that's all you say, that's bad. Page 199 Page 201 MR. SNAPP: Object to the form. 1 (Whereupon, Purdue-Wright-25 was 1 2 2 marked for identification.) A. There would be great reluctance to 3 market anything in this area with hydrocodone, 3 BY MS. SINGER: 4 and I felt that DEA would have strong feelings Q. All right. Exhibit 25. Exhibit 25 is 5 and DDMAC would have strong feelings against PDD8801176637, and it's an e-mail or memo from 6 making such claims. David Haddox to Robert Reder. When you have had 7 7 BY MS. SINGER: a chance to look at it, please just let me know. 8 8 (Witness reviewing document.) Q. And why is that? 9 9 A. Hydrocodone at the time was -- and for A. I've looked at it, ma'am. 10 most of the drug abuse epidemic has been more 10 Q. Okay. So do you recall this 11 abused than oxycodone or OxyContin. It is 11 communication? 12 12 prescribed in huge volume, it's used in acute A. No, ma'am. 13 13 pain and post-surgical, and it is also subject Q. Okay. And are you familiar with the 14 to -- I don't know, there isn't a term for this, program it discusses, MAD SS, or the MAD 15 15 but gray drug smuggling, the shipment of tablets surveillance system? 16 16 that look like pharmaceutically manufactured A. Misuse, abuse, and diversion. 17 17 tablets in the US from abroad. You know, I do Q. Okay. Is that how they --18 18 A. That was an acronym that we tried at not -- I'm not enough of a law enforcement 19 19 person to know who is smuggling them in or the one point. 20 20 actual volume, but I know that it was large Q. Okay. And were you involved with the 21 enough to distort the national statistics for 21 MAD surveillance system? 22 hydrocodone abuse. Hydrocodone is a bad drug of 22 A. Secondarily. That was predominantly abuse. Sid Schnoll and David Haddox. 23 23 24 Q. Okay. And so in that bullet point you 24 Q. And who was Sid Schnoll? 25 25 seem to be indicating that it's the advertising A. Sid Schnoll is one of my mentors. He

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was a senior researcher in drug abuse. He's a A. Not by that name. 2 2 member of the College of Problems of Drug Q. Okay. And do you know -- you were 3 Dependence, has had experience with previous 3 listed, if you can see under "Contacts," "Curtis 4 Wright (CRAC)." abuse epidemics, and was hired by Purdue. 4 5 5 O. So this communication describes a A. Mm-hmm. 6 6 study that Purdue seems to be set to undertake, Q. What does CRAC stand for? 7 is that correct? A. I've forgotten what that particular 8 A. Well, it describes a study that has 8 acronym, it disappeared about -- it disappeared. 9 9 been proposed, one of --Q. And so I take it you don't know who 10 10 Q. Go ahead -led this project? 11 A. Describes a study that had been 11 A. No. I don't know who -- I know about 12 12 proposed. the part I had in it, but I now found out that I 13 13 had a part in it because the project that we did Q. Do you know if Purdue ever undertook 14 14 that study? is reported here. 15 15 Q. Okay. A. I don't know whether they did it or 16 16 A. But I don't know about the project as not. 17 17 Q. And I notice that -- and it's a study a whole. 18 18 of -- potential study of addiction abuse, Q. Okay. So we'll get to your part, I 19 correct? 19 promise. 20 20 A. It is a potential study of abuse, So it says here in the "Background" 21 substance abuse disorders involving OxyContin, 21 section, "In the period 1999 through 2000 the 22 22 abuse of OxyContin. news media alleged several physicians had been 23 23 Q. And one of the people CC'd on this involved in large scale diversion of OxyContin 24 e-mail is HRU right after Dr. Kaiko, and PDG. 24 to the illicit market. This led to suggestions 25 25 Do you know who HRU is? that Purdue 'should have known' that these Page 203 Page 205 A. No. It would have to be a guess. physicians were engaged in these practices 1 2 2 Q. Do you think it might be Howard Udell? through routine examination of sales and 3 3 A. It might be Howard Udell. HRU, marketing data." 4 4 Howard, I don't know what Howard's middle Have I read that correctly? 5 initial is. 5 A. You've read that correctly. 6 Q. Okay. And do you recall whether the 6 Q. And do you recall a conversation 7 7 legal department or the general counsel was within Purdue about this issue? 8 involved in this potential study? 8 A. Not quite -- well, not stated quite 9 9 MR. SNAPP: Object to the form. that way. But Purdue certainly -- the people 10 A. I was not involved in the planning of 10 that talked to me were not -- certainly did not 11 the study, so I don't know. 11 want to be involved in promoting, marketing, 12 12 (Whereupon, Purdue-Wright-26 was selling, distributing, or otherwise having 13 13 marked for identification.) anything to do with physicians that were 14 BY MS. SINGER: 14 misprescribing or illicitly prescribing. And so 15 15 I'm learning some bits by reading this, but this Q. Okay. All right. Exhibit 26 is 16 PPLPC013000103821, and it's titled "Final Report 16 program looks like an attempt to say could 17 17 - Top 200 Project. January 2004." Purdue have known, should Purdue have known, 18 18 (Witness reviewing document.) what could Purdue have known from the sales and 19 19 Q. So something about the document made marketing data. 20 20 you smile. Q. And so if you look down to the --21 A. It meant that some work that we did 21 two-thirds down the page still at Bates number 22 actually got pushed up to -- and taken notice 22 821, it indicates that "Sales representatives 23 23 of. calling on physicians in the top sales cohort 24 Q. Okay. So do you recall the Top 200 24 were interviewed by experienced legal staff for

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indicators of illicit diversion."

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Project?

Page 204

Page 206 Page 208 1 Were you aware that that was 1 know. 2 2 happening? BY MS. SINGER: 3 3 A. I knew that there was some kind of O. Okay. But they --4 interviewing going on, but I didn't know who was 4 A. They have the ring, and the 5 doing it. definitions sound like something I might have 6 6 Q. Okay. And do you know why it was done kicked in. 7 by legal staff? 7 Q. Okay. But they did make it into this 8 A. No. 8 document on the Top 200 Project? 9 9 Q. And did you see any of the results of MR. SNAPP: Object to the form. those interviews from them? 10 10 BY MS. SINGER: 11 A. No. 11 Q. Is that correct? 12 12 A. Well, it got into this document. Q. And were you involved in any way in 13 13 that process? Q. Okay. And do you know what sources of 14 14 A. It's extremely hard to answer that information Purdue relied on in either coming up 15 15 because I can't tell if some question that I got with these categories or identifying doctors who 16 bombing in by e-mail from someone was related to might belong in either of them? 17 17 this or not. I answered a lot of questions MR. SNAPP: Object to the form. 18 18 about what could be looked for in talking to --A. I can only talk about my part, the 19 and looking at a clinic or making a sales call 19 analysis that we did --20 20 or doing a -- talking to a pharmacy or -- I BY MS. SINGER: 21 21 would get questions and I wouldn't know why I Q. Okay. 22 was being asked. 22 A. -- as part -- that I think are part of 23 23 Q. Okay. And I think we may have talked this. 24 about this before, but do you remember who those 24 Q. Okay. Please go ahead. 25 25 questions came from? A. And what -- there were several Page 207 Page 209 sources. Dr. Haddox's program, Sid's program, 1 A. I'm tempted to say everybody. I got 2 questions from a number of different sources. 2 the RADARS program had found some very startling 3 3 After I checked that they were Purdue employees information because they had concurrent abuse 4 and had a right to ask, I answered the question. 4 and diversion data by ZIP code for areas that it 5 Q. Okay. If you turn to Bates number 5 turned out that there had been a diverting 6 823, you'll see in bolded text categories of pharmacy or physician, and by statistical 7 "Impaired Physicians" and "Felonious analysis you could see that one or two of some 8 Physicians." of these diverting pharmacies or physicians had 9 9 Did you hear those terms used within an enormous impact, they were capable of putting 10 10 in a very large number of dosage forms into the Purdue? 11 11 illicit market and showed up as drug abuse A. I think I might have been responsible 12 12 for them. cases. That was one source. 13 13 Q. That includes the third category at The other source was as part of our 14 Bates number 824, "Diverting Physicians"? 14 project we went and tried to find all of the 15 15 A. I think that might have been language cases around the country of people who were 16 16 that I came up with in response to a question. charged and convicted of diversion of 17 17 pharmaceuticals, and then we did an analysis to I'm not sure. 18 18 Q. Okay. And so Purdue was aware that find out what common factors we could find that 19 19 there were doctors who fit, to use your prior might tell you that the person is one of these 20 20 phrase, in each of these domains? 21 MR. SNAPP: Object to the form. 21 Q. Do you recall who the "we" was that 22 22 conducted that analysis? A. I don't know what Purdue was aware of. 23 23 I made up -- if these are mine and they look --A. Well, that analysis, that was my 24 they have the ring of my speech, but it could 24 group. Nab Dasgupta was the lead investigator

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have been David, it could have been Sid, I don't

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on -- was the lead person on that.

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- Q. And do you remember what the time frame was for doing this inquiry? Yes, the dreaded date question.
- A. It was in the new -- all I can tell you it was in the new building, so it would have had to have been after the move to the new building. It was after Nab came on board, and I don't know his start date. So it was somewhere in the 2003, 2004, or maybe 2000 -- I think -- I'm not sure. It would have been 2003, 2004.
- Q. And do you remember as part of this process whether you identified specific prescribers who --
  - A. We did.
- Q. Yes.

- A. We did, yes, because they had been criminally charged and convicted, so we had their names.
- Q. And did you identify any physicians who hadn't been criminally charged or investigated?

MR. SNAPP: Object to the form.

- A. No. We used them as aggregate data. BY MS. SINGER:
  - Q. Tell me what you mean by that.

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A. Okay. There are two ways that you can treat personal data, and one invades the privacy of the person and the other does not invade the privacy of the person, and there is ethics involved with that.

So for the physicians that we used as our test group, they were people that we had IMS data on but did not know their -- we pulled their names out of the files.

O. Got it.

And did you use any external consultants in the project?

MR. SNAPP: Object to the form.

- A. I don't know what the other parts of the project did. I just know what we did, and we didn't. Our part, we didn't.
- 17 BY MS. SINGER:
  - Q. Okay. And so under the category of Diverting Physicians at the top of Bates number 824, they're described as "providers engaged full-time in the illicit diversion of narcotics." Is that accurate? Was that a yes?
    - A. That is a yes. "These providers engaged full-time in the illicit diversion of narcotics."

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Q. Were those the prescribers who had been identified from the prescribers who had been charged or convicted?

MR. SNAPP: Object to the form.

A. Yes, they were.

BY MS. SINGER:

- Q. And if you turn to Bates number 825, the second full paragraph, "These two factors," could you read that out loud?
- A. "These two factors (excessive narcotics prescriptions filled for cash and failure to prescribe enough of the needed lower strengths) proved to be very specific predictors of aberrancy."
  - Q. Stop there, please.
    Can you explain what that means?
    MR. SNAPP: Object to the form.

A. For diversion, the highest strengths, the 160 when it was available, the 80 when it was not, were the target strengths, that's what you want to get, you want to get prescriptions for that because you are going to make the most money off of that. But most patients do not need 80 milligrams of OxyContin, they don't -- many of them don't need 40. I mean, I think the

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median dose prescribed was the 20.

And so if you are looking at a prescription profile for a clinic or for a pharmacy for that matter, and you see no 20s, you know, no 40s, a little bit of 40s, and then this huge blip of 80s, that's suspicious because that's not what the patients need.

Q. Okay. And then what about the excessive narcotics prescriptions filled for cash?

MR. SNAPP: Object to the form.

A. Most people today have some form of health insurance, either from the government, through Medicare or Medicaid, or from private health insurance. If people are showing up and are buying their prescriptions from cash, or in the case of dispensing physicians he's literally selling the drugs out of the medical office -- dispensing is legal in some states -- for cash, no credit cards, no checks, please, nothing but cash, that's suspicious.

# BY MS. SINGER:

Q. Okay. And it says at Paragraph 4 at the bottom of the page, so having identified these factors for prescribers, Paragraph 4 says

Page 214 "We should examine pharmacy operations using a A. I believe I still am a member, but I 2 similar technique to see if there are any have to check whether I paid this year's dues. 3 predictors that might identify pharmacies 3 Q. My guess is they'll find you. 4 involved in the illicit trade." 4 All right. If you can turn to the slide that is titled "Disaster." It is towards 5 5 And you're nodding your head. 6 A. I'm saying that is what -- you read 6 the front of the deck. Can you read the first 7 that correctly. 7 bullet and the points underneath it, please? 8 Q. Okay. Do you know if Purdue undertook 8 A. "Unanticipated widespread abuse of a 9 9 that work? prescription medication is a disaster for: 10 10 "The patients. A. No, I don't know if it was done. But 11 I don't know whether it was done or wasn't done. 11 "The prescribers. 12 12 Q. Okay. Did your group ever did that? "The public. 13 13 A. I don't know. Nab would have done it The company." 14 14 or the epidemiologist would have done it, and And "The Agents of Social Control. 15 they might have done it without my necessarily 15 (DEA, FDA, NIDA, Police, Politicians, 16 knowing it. 16 Prosecutions....)" 17 Q. Okay. We'll come back to that. 17 Q. Do you agree with the statement here 18 18 Okay. A lot of ink went into this that "widespread abuse of a prescription 19 exhibit. So this is Exhibit Number --19 medication is a disaster"? 20 20 MS. FORSTER: 27. MR. SNAPP: Object to the form. 21 21 A. I believe that I probably said this, BY MS. SINGER: 22 22 Q. -- 27, and I don't think it had a and I believe it to be true. It is a very bad 23 23 native Bates number to it. So it is "Risk thing. 24 Identification, Risk Assessment and Management 24 BY MS. SINGER: 25 25 of Drug Formulation (A Regulated Company Q. And when you talk about agents of Page 215 Page 217 Perspective)." 1 1 social control, tell us how you mean that. 2 2 (Whereupon, Purdue-Wright-27 was A. Well, I made it up because I didn't 3 marked for identification.) know how to fit -- or I think I made it up. I 4 MR. SNAPP: I'm sorry, for the record, didn't know how to fit --5 if it didn't have a Bates number, where did it 5 Q. I don't think they call themselves 6 come from. 6 that. 7 7 MS. SINGER: It was produced by A. I don't think they call themselves 8 that, but I couldn't figure out how to make DEA Purdue. I think it was just produced without a 9 9 native cover to it with the Bates number, but we and FDA and NIDA and police and politicians and 10 can search and clarify the record. 10 prosecutors all fit together in one term, so it 11 11 looks like I made up a term. BY MS. SINGER: 12 And they're people who are responsible 12 Q. So, Dr. Wright, do you recognize this 13 13 for the smooth and orderly functioning of presentation? 14 (Witness reviewing document.) 14 society. They are supposed to make things go 15 15 A. Well, this is a draft of a well. 16 16 presentation that I may have given to the Q. Okay. All right. Let's turn to --17 17 College on Problems of Drug Dependence. (Whereupon, Purdue-Wright-28 was 18 18 Q. And what is the College on Problems of marked for identification.) 19 19 Drug Dependence? BY MS. SINGER: 20 20 A. It's a group -- it's a members Q. We'll start Exhibit 28, it's another 21 organization, scientific organization that has 21 native production. So this did have a Bates 22 existed for some time that is individuals who 22 number of PPLPC013000106089, and it's titled 23 are concerned with drug abuse, dependence, and 23 "Data Analysis Program, 1Q2004 Update" by 24 medication safety. 24 Nabarun Dasgupta. 25 Q. And you were a member of that? 25 A. Yes, that's how you spell his name,

п	ignly Confidential - Subject to	J 1.	archer confractionality Review
	Page 218		Page 220
1	Nabarun Dasgupta, we called him Nab. I think he	1	big and sifts out all of the cases that you're
2	he's finished his Ph.D by now. And he's a	2	interested in into a little tiny bucket over
3	super, super smart little scientist.	3	here.
4	Q. And you've now memorialized that,	4	Q. Okay.
5	he'll be grateful.	5	A. And some statistician will not think I
6	So that is the Nab you've been talking	6	described it very well.
7	about before?	7	Q. So this is the technique that
8	A. Yes.	8	Dr. Dasgupta used to identify the factors that
9	Q. Have you seen this presentation	9	were predictive of diversion or variant
10	before?	10	prescribing, correct?
11	A. I don't remember it specifically, but	11	MR. SNAPP: Object to the form.
12	it looks like Nab's presentation.	12	A. That's the technique.
13	Q. Okay. And does it reflect the work	13	BY MS. SINGER:
14	you were talking about earlier that you were	14	Q. And this is the technique that allowed
15	doing in analyzing prescribers and types of	15	you to identify that it was high dose and high
16	prescribers who were engaged in diversion or	16	cash prescribers who were of greatest concern?
17	inappropriate prescribing?	17	MR. SNAPP: Object to the form.
18	MR. SNAPP: Object to the form.	18	A. Nab Dasgupta used a number of this
19	(Witness reviewing document.)	19	was one analysis, he did a number of analysis,
20	A. I think so.	20	and he used a number of partitioning variables.
21	BY MS. SINGER:	21	Looking at his results here on the slide, he
22	Q. Okay. I want to turn your attention	22	started out with 200,000 total and 142
23	to the slide "Screening by Recursive	23	identified aberrant prescribers, and not
24	Partitioning."	24	prescribing enough of the lower strengths, split
25	A. Yes, ma'am.	25	them up a little bit, total net cash sales,
			,,
	Page 219		Page 221
1	Page 219 Q. And does this first of all, do you	1	Page 221
1 2	_	1 2	•
	Q. And does this first of all, do you		Page 221 split them up a little bit, percentage ever cash RX, split them up a little bit, and he ended up
2	Q. And does this first of all, do you know what recursive partitioning is?	2	Page 221 split them up a little bit, percentage ever cash
2 3	<ul><li>Q. And does this first of all, do you</li><li>know what recursive partitioning is?</li><li>A. Yes.</li></ul>	2	Page 221 split them up a little bit, percentage ever cash RX, split them up a little bit, and he ended up with what it says here, 100, Top 100 Project, I
2 3 4	<ul><li>Q. And does this first of all, do you</li><li>know what recursive partitioning is?</li><li>A. Yes.</li><li>Q. What is it?</li></ul>	2 3 4	Page 221 split them up a little bit, percentage ever cash RX, split them up a little bit, and he ended up with what it says here, 100, Top 100 Project, I still don't know the name, that he describes.
2 3 4 5	<ul> <li>Q. And does this first of all, do you know what recursive partitioning is?</li> <li>A. Yes.</li> <li>Q. What is it?</li> <li>A. It's a statistical technique available</li> </ul>	2 3 4 5	Page 221 split them up a little bit, percentage ever cash RX, split them up a little bit, and he ended up with what it says here, 100, Top 100 Project, I still don't know the name, that he describes. And what he describes are physicians in trouble.
2 3 4 5 6	<ul> <li>Q. And does this first of all, do you know what recursive partitioning is?</li> <li>A. Yes.</li> <li>Q. What is it?</li> <li>A. It's a statistical technique available in most of the major high-end statistical</li> </ul>	2 3 4 5 6	Page 221 split them up a little bit, percentage ever cash RX, split them up a little bit, and he ended up with what it says here, 100, Top 100 Project, I still don't know the name, that he describes. And what he describes are physicians in trouble. BY MS. SINGER:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And does this first of all, do you know what recursive partitioning is?  A. Yes. Q. What is it? A. It's a statistical technique available in most of the major high-end statistical programs. And what it enables you to do is you have some cases and you have some controls, people who have it, people who don't, people who are diverters, people who may or may not be diverters, and they're all mixed together. You can take a categorical variable and move across the values for that variable, in other words try different numbers that you plug in, and see how well it splits the main body of data. Okay.  And then you can add another variable, and then you can move the variables up or down in doing which one first and which one second. So it's a statistical technique where you sit there at the computer and you plug numbers in and you see how	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Page 221 split them up a little bit, percentage ever cash RX, split them up a little bit, and he ended up with what it says here, 100, Top 100 Project, I still don't know the name, that he describes.  And what he describes are physicians in trouble. BY MS. SINGER:  Q. Okay. And I want to turn also to "Risk Factors." So explain what risk factors are in this context.  A. Okay. In epidemiologic studies risk factors are things that say these are associated with the cases more than with the rest of the population. These are things that happen more in whatever you're looking at, tuberculosis, leprosy, drug aberrant drug prescribing, they're more likely to be, and they are more likely to have, and if you see these things then you need to be concerned that they may have the target behavior, disease, condition.  Does that help?  Q. It does. Thank you.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And does this first of all, do you know what recursive partitioning is?  A. Yes. Q. What is it? A. It's a statistical technique available in most of the major high-end statistical programs. And what it enables you to do is you have some cases and you have some controls, people who have it, people who don't, people who are diverters, people who may or may not be diverters, and they're all mixed together. You can take a categorical variable and move across the values for that variable, in other words try different numbers that you plug in, and see how well it splits the main body of data. Okay.  And then you can add another variable, and then you can move the variables up or down in doing which one first and which one second. So it's a statistical technique where you sit there at the computer and you plug numbers in and you see how	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Page 221 split them up a little bit, percentage ever cash RX, split them up a little bit, and he ended up with what it says here, 100, Top 100 Project, I still don't know the name, that he describes.  And what he describes are physicians in trouble. BY MS. SINGER:  Q. Okay. And I want to turn also to "Risk Factors." So explain what risk factors are in this context.  A. Okay. In epidemiologic studies risk factors are things that say these are associated with the cases more than with the rest of the population. These are things that happen more in whatever you're looking at, tuberculosis, leprosy, drug aberrant drug prescribing, they're more likely to be, and they are more likely to have, and if you see these things then you need to be concerned that they may have the target behavior, disease, condition.  Does that help?  Q. It does. Thank you.

found protective factors.

indicators that takes a population that's this

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Page 222 Page 224 1 Q. That's right. 1 attention? 2 2 A. And then he reached his conclusions Q. I wouldn't dare stop you. 3 3 which are that bankruptcy, debt is a risk factor A. If you look at the last page of this 4 for suspected criminal prescribing. Large element, I just want to bring up the fact that 5 volume prescribing of opiates by a if you look at the states that were involved in 6 6 non-specialist is a risk factor. Pain the state medical board sanctions. Florida leads 7 specialization appears to be a protective the state and leads the count. And it turns out 8 factor. And simply screening what's currently that dispensing from your office is a risky 9 practice in terms of diversion, abuse, and available on the internet for everybody, you, 10 10 me, everybody, has some efficacy. diversion of opioids. 11 Q. So let's go back to two of them. 11 Q. Meaning it's often predictive, it's in 12 12 Internet screening, you mean just that category of factors? 13 13 doing internet research on a doctor? A. It's in those categories of factors. 14 14 MR. SNAPP: Object to the form. I believe Florida has been concerned and has 15 15 BY MS. SINGER: done something about that. 16 16 (Whereupon, Purdue-Wright-29 was Q. Is that right? 17 17 A. Okay. Nab purchased, and I do not marked for identification.) 18 18 remember the name of the service, but he BY MS. SINGER: 19 19 purchased -- at that time there was an internet O. So Exhibit 29 is an article, it 20 20 doesn't have a Bates number, "Association service that would tell you about someone, pull 21 21 all their records, see if they were in legal between non-medical and prescriptive use of 22 22 opioids." And the lead author is Dr. Dasgupta, proceedings, scan them for whatever could be 23 23 found in the public domain, and Nab thought it correct? 24 would be useful, and that's what he meant by 24 A. Yes. 25 25 internet screening. So he would plug in this Q. And are you also listed as an author? Page 223 Page 225 target doctor's name that we knew about, and say 1 A. This is pretty much my entire group. 1 2 2 what do we get on him? And we got back that Q. Okay. So everybody listed among the 3 3 authors are Purdue Pharma employees who worked he'd been divorced, that he's declared 4 4 for you or with you? bankruptcy twice, that he was in arrears on his 5 5 taxes, and a whole bunch of stuff. And those A. Well, they didn't work for me. 6 were the factors that Nab said could you use Salvatore Carino was the computer guy in 7 that, could that work, would that help you. marketing who had the IMS data that we used, and 8 Q. And his answer was yes, correct? so he was the one that had to make the data 9 A. He thought so. 9 available to us and make it available in a form 10 10 MR. SNAPP: Object to the form. that we could use. 11 11 BY MS. SINGER: Meredith Smith was the epidemiologist 12 12 Q. And then non-specialist status, just that was hired to service both Dr. Haddox and 13 13 to make sure we understand that, a myself in that group. David Haddox, myself, 14 non-specialist, you're talking about a family 14 Doug Kramer, medical officer, and Mary-Ann 15 15 Zalman was the medical writer. I remembered who practitioner or general practitioner, is that 16 16 she is at last. accurate? 17 17 Q. All right. So you recognize this MR. SNAPP: Object to the form. 18 18 article as one you all participated in, correct? A. Family practice is actually a 19 19 A. Yes. specialty now. So it would be someone who 20 20 didn't do a residency. Q. If we turn to Page 141. And by the 21 BY MS. SINGER: 21 way, let's just put the date on the record. The Q. So, for instance, a primary care --22 22 date of the publication is 2006, correct? 23

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25

A. General practitioner essentially.

Can I bring something to your

well, not necessarily.

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A. (Nodding in the affirmative).

Q. So if we turn to Page 141. So if you

look on the top paragraph of the first column,

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can you read the sentence beginning "The remarkable constancy"?

- A. "The remarkable constancy of the relationship of drug abuse sequelae to the magnitude of prescriptive usage, among opioids, suggests that as legitimate use of an opioid medication increases, the prevalence of non-medical use and its consequences increase as well."
- Q. Okay. And does that correctly reflect the conclusions you reached as a result of your study?
- A. That is the primary conclusion of the study, along with the secondary finding that it didn't matter what the drug was.
- Q. And so can you -- the sentence you read out loud, can you restate that in more lay terms, please?

MR. SNAPP: Object to the form.

20 A. Yes.

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BY MS. SINGER:

- Q. Could you do that?
- 23 A. Yes. We have a control system in this 24 country that is intended to prevent drugs 25 leaking out of the prescriptive proper use for a

A. Number of cases.

- Q. And in reaching this conclusion you
- relied again on DAWN ED data, correct?
  - A. The sources of this data were
- multiple. One was the DAWN emergency department

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- data which was -- had some problems because they
- changed -- periodically they change those
- surveys and assure us that everything is okay.
- Sometimes statistically they're not. And we
- 10 then had to use the IMS data for how many kilos
- 11 of oxycodone, how many kilos of hydrocodone, how
  - many kilos of fentanyl, how many kilos of
- 13 morphine were in the pharmaceutical pipeline, so
- 14 we had to reduce all of the companies that made
- 15 morphine down to a total, and then we had to
- 16 adjust so that we were adding the right amount
- of morphine and the right amount of oxycodone 17
- 18 and the right amount of fentanyl, converting it

19 all to morphine equivalence. 20

Clear so far?

Q. Crystal.

22 So effectively, DAWN ED data gave you 23 the measure of abuse, correct?

A. It was a surrogate measure of abuse.

MR. SNAPP: Object to the form.

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- 1 patient. Our -- my hypothesis going in, and it
- 2 was my hypothesis, is that has a certain
- 3 percentage effectiveness. Some percent of the
- 4 drugs that are intended to get to patients leak
- 5 out. When they leak out, if they leak out in a
- 6 fixed amount, then the number of cases will be
- 7 constant. There's so many drug addicts who are
- 8 diverting them. If it's a percentage, you know,
- 9 the system is 99.9 percent effective, say, then
  - as you put more drugs into the prescriptive drug
- 11 flow, as there are more in the marketplace, as
- 12 there's more in the pharmacies, as they're more
- 13 in the prescriptions, as there's more in the
- 14 medicine cabinets at home, more will leak out.

So given the given set of controls that were operative during the period of this study, the more prescription drugs you had in the marketplace the more drug abuse cases you would have.

- Q. And what was the period of the study?
- A. You would ask that. 1994 to 2002.
- Q. Okay. And so going back to how you presented this, it is not a fixed amount, it is a percentage, so you increase the volume you increase the --

- BY MS. SINGER:
  - Q. And the IMS data gave you have the volume of supply, correct?
    - MR. SNAPP: Object to the form.
  - A. The IMS data gave us an approx -- a good approximation of the amount of each opioid in the supply chain.
  - BY MS. SINGER:
  - Q. And DAWN ED data, as you've noted, only picks up people who show up in hospitals, correct?
  - A. Emergency departments. And it's pretty good.
  - Q. Okay. Does it get at the number of people who may be addicted or abusing who don't end up overdosing?

MR. SNAPP: Object to the form.

A. Okay. DAWN ED data will not detect someone who has not had a medical encounter. However, the likelihood of a medical encounter for someone who is seriously abusing drugs is so high that sooner or later they'll end up in the emergency room.

- BY MS. SINGER:
  - Q. Okay. One last question about IMS

Page 230 Page 232 1 data. We're going to go back to the GAO report, 1 analysis? 2 2 which was --MR. SNAPP: Object to the form. 3 MS. FORSTER: Exhibit 19. 3 A. I cannot be sure, but I think maybe I 4 4 BY MS. SINGER: had a hand in answering a question that led to 5 5 Q. -- Exhibit 19, please. the 11 factors that they were looking for in 6 Do you recall when you began using IMS 6 that discussion, in what I just read, at least I 7 7 and DAWN data to identify abuse, diversion, and hope so. 8 8 problem prescribing? BY MS. SINGER: 9 MR. SNAPP: Object to the form. 9 Q. And do you recall, in the few years 10 10 A. Okay. I only know when we began to you were at Purdue before then, any energy 11 analyze the data, and I don't know that very 11 within the company to turn those kinds of data 12 12 precisely, but it was in the new building and it sources to use for compliance and preventing 13 13 diversion, and not just for sales? was after Nab came, so I'm thinking likely to be 14 14 2004, 2005. MR. SNAPP: Object to the form. 15 15 BY MS. SINGER: A. Yes, I was one. 16 Q. Okay. And Purdue had had IMS data 16 BY MS. SINGER: 17 17 prior to 2004, 2005, right? Q. And beyond you? 18 18 A. I do not know for sure, but I'm sure MR. SNAPP: Object to the form. 19 they did. 19 A. I don't know, because the -- when I 20 20 Q. Okay. And if I can turn you to was working with the few contacts we had in 21 Page 40 of the GAO report. The bottom paragraph 21 sales on the programs that we've already went 22 starts "Since the launch." 22 through and described, they were very concerned 23 23 A. Mm-hmm. about how they might use this data, about what 24 Q. Do you mind just reading the paragraph 24 techniques are available, but there had been 25 25 on into the next page out loud, please? some egregious mistakes made that made them very Page 231 Page 233 1 A. "Since the launch of OxyContin, Purdue 1 concerned about using them properly. 2 2 has provided its sales force with considerable On one occasion I heard a report 3 3 information to help target physicians and secondhand, I can't verify that it's true, that 4 prioritize sales contacts within a sales 4 the DEA came in black jacket and boots to a 5 territory. Sales representatives routinely 5 pharmacy because they were prescribing so many 6 receive daily, weekly, monthly, and quarterly opioids, and it turns out that they were the 7 physician prescribing reports based on IMS pharmacy that filled for a major cancer center. 8 8 So the problem was not how to -- the Health data that specify the physicians who have 9 9 written prescriptions for OxyContin and other problem was not the IMS data existed, it's how 10 10 opioid analgesics, and the number of to use it and how to tell good from bad when 11 11 prescriptions written." you're using it. 12 12 Q. Go ahead and read the next sentence. BY MS. SINGER: 13 13 A. "Although this information has always O. And in terms of that conversation 14 been available for use by Purdue and its sales 14 about how to use the data and the 11 factors and 15 15 representatives, it was not until fall 2002 that those things you've talked about, was there 16 16 Purdue directed its sales representatives to anything before Dr. Dasgupta's report that 17 17 begin using 11 indicators to identify possible really gave a direction to that? 18 18 abuse and diversion and to report the incidents MR. SNAPP: Object to the form. 19 19 to Purdue's General Counsel's Office for A. You asked me if there was anything 20 20 investigation." before Dr. Dasgupta's report which came out in 21 Q. Okay. You can stop there. Thank you 21 2006 that gave direction to that, and Dr. Haddox 22 22 for reading that. and Dr. Schnoll were both very vocal in this 23

area.

BY MS. SINGER:

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Were there any discussions that you

can recall in Purdue, within Purdue, about using

IMS data for compliance before you began your

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Q. And what did their work produce?

Page 234 Page 236 1 A. I don't know, because concerns about 1 is missing from my copy. 2 2 marketing, sales reps, and prescribing, and MS. SINGER: We can sub one in. 3 especially improper detailing or improper 3 MR. SNAPP: I just want to make sure 4 prescribing, would have been handled by the 4 the witness is --5 ethics group, and they did not tell the rest of 5 A. I'm missing the end of it. 6 6 us what they were finding. BY MS. SINGER: 7 7 Q. And who was the ethics group? Q. What's your last Bates number? A. The chief ethical officer was Howard 8 8 MR. PETRILLO: I think the witness's 9 9 Udell. And if -- I mean, we all knew that if we copy is also missing 34. And the last Bates 10 10 had anything we were concerned about in the number is 41. 11 company at all ever to go directly to him. 11 MS. SINGER: Okay. All right. We've 12 12 Q. And Howard Udell ultimately ended up had some copying issues. 13 13 pleading guilty, correct, in the 2007 --A. In answer to your question, except for 14 14 MR. SNAPP: Object to the form. the fact that it's missing bits, this appears to 15 15 A. I don't know the details of any of be my integrated summary of safety. 16 that. That happened after I left the company. 16 BY MS. SINGER: 17 MS. SINGER: Okay. Let's leave it. 17 Q. Okay. So what we'll do is during the 18 18 If I can just take five minutes and next break we will provide you all with complete 19 check my notes, and then we'll be done and pass 19 copies. 20 20 the baton. In the interim I just want to direct 21 21 THE VIDEOGRAPHER: We are now going Dr. Wright's attention to Bates number 40, 22 22 fortunately one of the Bates numbers you have. off the record, and the time is 3:58 p.m. 23 23 (Whereupon, a recess was taken.) A. No. 24 THE VIDEOGRAPHER: We are now going 24 Q. No? 25 back on the record, and the time is 4:08 p.m. 25 A. I go from 37 to 39 to 41. Page 235 Page 237 1 Q. Okay. We will deal with that on the 1 BY MS. SINGER: 2 2 next questioning. My apologies for that. Q. All right. Dr. Wright, we had talked 3 3 about the integrated safety study earlier, and Okay. We talked earlier this morning, 4 it took us a minute to find a copy of it, but 4 a lifetime ago, about the duties of a 5 Exhibit 31 is PDD7024302094. 5 responsible pharmaceutical company, and you 6 (Whereupon, Purdue-Wright-31 was talked about what you thought were the elements 7 7 marked for identification.) or hallmarks of that. And we talked about the 8 8 BY MS. SINGER: role of the package insert. 9 9 Q. Is that right? No, I read the wrong Now, is it accurate to say that in your view the role of the package insert is to 10 Bates number and gave you the right document. 10 11 The correct Bates number is PDD1501090033. 11 convey full and accurate information to the 12 12 When you've had a chance, whenever prescriber about how and when to use the 13 13 you've had a chance, let us know if you product? 14 recognize that to be the integrated summary of 14 MR. SNAPP: Object to the form. 15 15 safety for OxyContin. A. The intent of the package insert is 16 16 MR. SNAPP: Do you have another copy? to, from my perspective now, convey mutual 17 17 MS. SINGER: I gave two. information that is agreed to by both the 18 18 (Witness reviewing document.) company and the FDA about what is known about 19 19 MR. SNAPP: Looks like it's missing a the drug both from a scientific perspective and 20 20 in terms of what the experience has been with Bates number. 21 21 it, and the usage of the product in a proper MS. SINGER: Excuse me? 22 MR. SNAPP: My copy is missing Page 1 22 fashion. It's not nearly enough to use any of 23 these drugs. There's a whole bunch of other 23 of the document.

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MS. SINGER: So it's in the form --

MR. SNAPP: It skips from 33 to 35, 34

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things that the practitioner must bring to the

interaction with the patient. But it's an

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agreed to starting point for both the company
 and the prescriber.

# BY MS. SINGER:

- Q. You said it reflects the scientific knowledge and clinical experience at the time the package insert is drafted, correct?
  - A. That's correct, ma'am.
- Q. And the scientific studies evolve over time? There's more scientific knowledge, correct?
  - A. That is correct, ma'am.
- Q. And there's more clinical experience as the drug is used in the general population, correct?

MR. SNAPP: Object to the form.

A. I believe that is to be correct, too.

### BY MS. SINGER:

Q. And is it fair to say that in your opinion and experience, a responsible company takes advantage of that scientific knowledge and clinical experience to make sure that the package insert continues to accurately reflect what is known about the drug?

MR. SNAPP: Object to the form.

A. That's difficult, and it's difficult

not, again, your experience and your impression that a package insert remains fixed in time?

- A. Package inserts, to my knowledge, are changed as significant new knowledge accrues.
- Q. And the purpose, again, of reflecting that new important or significant information in the package insert is to make sure that the prescription drug is used safely and effectively in the population, correct?

MR. SNAPP: Object to the form.

- A. Purpose is a bit difficult, but it is in the public interest that a package insert that requires modification gets modified. BY MS. SINGER:
- Q. And again, so that prescribers have the important information, not necessarily all of the information, to make decisions about how to guide and use the product with their patients?

MR. SNAPP: Object to the form.

A. The purpose is to enable pharmacists, prescribers, and these days health insurers, sadly or to benefit, what the drug does, how to use it safely, and what is known about its toxicity and problems.

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because changing the package insert is a huge undertaking both for the company and for the FDA. Either the FDA can request changes in the package insert, or the company can request changes in the package insert through a process of amendment of the NDA.

Where my knowledge fails, because there have been changes since -- there were changes when I was at the FDA and there have been changes since I was at the FDA, and it was covered -- and it's the responsibility of DDMAC, when to make a change, why to make a change, what change to make all are things that drug advertising has strong -- has control over and has strong input into.

There's also the question of providing what are called reprints to the physician which are updates on science that has been done since the drug was approved, and there are complex rules that I do not -- I'm not up to today on on how you may do that, when you may do that, if they have to request it, if you can offer it, all of which are beyond my knowledge and skill. BY MS. SINGER:

Q. So given all of that, it's certainly

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MS. SINGER: Okay. All right. I have nothing further at this point.

THE VIDEOGRAPHER: Should we go off? MR. STEWART: Take about five minutes.

THE VIDEOGRAPHER: We are now going off the record, and the time is 4:17 p.m.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: We are now going back on the record, and the time is 4:31 p.m.

# **EXAMINATION**

#### BY MR. STEWART:

Q. I'm Mike Stewart, I represent a number of plaintiffs in the State of Tennessee, including a number of district attorneys general.

I'm going to state the terms of our agreement whereby we're having this discussion today with your counsel and give him the opportunity to respond.

But I'm planning to take just two hours of testimony, and I've agreed I don't plan to come back and take additional testimony from you in this case. If there is a situation where some particularly significant document has turned up that we have not received, then we may

Page 242 Page 244 1 seek to depose you on that issue. However, value, and total street value. 2 2 we'll work with your counsel to minimize any Q. Is that a list, do you think, of 3 inconvenience involved, whether by telephone or 3 prescribers? Can you tell? And you may want to 4 look at the prior page to see if that's correct. perhaps a very short follow-on deposition. 5 5 A. It looks like a list of the 44 MR. STEWART: Does that make sense? 6 6 aberrant prescribers. MR. SNAPP: That's agreed. 7 7 MR. PETRILLO: That does make sense. Q. Did you -- I'll tell you our review of 8 I just want to say as a practical matter, I take the -- or can you tell, on that list of aberrant 9 prescribers, can you tell if there's an it that you agree that if the documents have 10 been produced as of today that the document will 10 identifier that would show you which prescriber 11 not be a cause for additional deposition time. 11 it is? 12 12 MR. STEWART: That makes sense. The A. If you knew what the ME number meant 13 13 and the IMS ID meant, then you could tell who only thing I would say is there is actually a 14 14 dispute in this case, which I think you're the prescriber was. 15 15 unaware of, about whether documents produced Q. Looking at this today, if I told you 16 16 have been done in a form that works. But I that three of those prescribers are from the 17 17 think you can see that we're going to try to be State of Tennessee, I take it you couldn't 18 18 reasonable. Yes, if we've had a good contradict or confirm it one way or the other? 19 19 opportunity to review it, then that would be MR. SNAPP: Object to the form. 20 20 true. A. I could not tell. 21 21 MR. PETRILLO: Okay. That's fine. BY MR. STEWART: 22 22 And we'll be reasonable, too. Q. But you know there are numbers on that 23 23 And we're doing this in lieu of a document that would allow us to correlate that 24 formal notice of deposition which we did not 24 document to particular prescribers? 25 25 MR. SNAPP: Object to the form. receive from this particular party, so I would Page 243 Page 245 advise that we proceed. A. If you had the codes you could. 1 1 2 BY MR. STEWART: THE WITNESS: I will proceed. 2 3 3 Q. Turn now to another exhibit that BY MR. STEWART: 4 4 you've already been handed, which is Exhibit 28. Q. Thank you. 5 5 With that, sir, I'd ask you to turn to That's this PowerPoint presentation that you 6 Exhibit 26, which I think is the second one in 6 have already reviewed. 7 7 your pile, and you've already looked at it. Do you recall that? 8 Do you remember reviewing Exhibit 26? 8 A. I remember it. 9 9 A. I remember looking at it. Q. Okay. Do you remember Exhibit 28 as a 10 Q. Can you turn to the very last page 10 document entitled "Data Analysis Program," first 11 where I think you'll find a list of providers, I 11 Quarter 2004 Update? 12 12 believe? Is that what the last page of A. Yes, I do. 13 13 Exhibit 26 has? Q. I'll tell you I put, just so we can 14 A. The last page of Exhibit 26 looks like 14 move quickly, a green sticky on that document 15 15 a representative sample data. which should lead you to a page entitled 16 16 "Screening by Recursive Partitioning." Q. And what sort of sample data? Can you 17 17 tell by the title and how it's incorporated into Do you see that? 18 18 the document what that list is showing us? A. Yes, I do. 19 19 A. There is an identifier, which I don't Q. Okay. And my question is, do you know if Purdue, after this analysis that's embodied 20 know what it means and would need those codes to 20 21 know what it means. Narcotic treatments, 21 in this PowerPoint was conducted, did it follow 22 OxyContin treatments, percent cash treatment, 22 up to analyze those doctors that had 10 to 23 23 20-milligram OxyContins representing less than hydrocodone street value, methadone street 24 value, fentanyl street value, morphine street 24 35 percent of all OxyContin prescription sales? 25 25 value, oxycodone street value, OxyContin street MR. SNAPP: Object to the form.

Page 246 Page 248 1 A. I don't know. A. Yes, I do. 2 BY MR. STEWART: Q. Can you look at Exhibit 32 and tell me 3 3 O. Do you know, looking at the second whether or not you recognize it as a document 4 bullet, if Purdue ever followed up to analyze that you authored? And I'll point out the last 5 5 page of the document ends with the word "Curt." the doctors whose patients paid more than 6 100,000 in cash for narcotic analgesic A. I do not remember the document, but I 7 prescriptions to determine whether those doctors have no reason to believe I did not author it. 8 8 were involved in diversion? Q. Looking at the substance, do you see 9 9 that the document contains a series of points MR. SNAPP: Object to the form. 10 10 A. I don't know. under headings which are entitled "Costs 11 BY MR. STEWART: 11 associated with criminal diversion," "By patient 12 12 diversion," and so forth? Do you see that? Q. Do you know if Purdue ever followed 13 13 up, looking at the third bullet, to analyze A. Yes, I do. 14 14 those doctors who had 17 percent of their Q. Are these lists consistent with your 15 15 prescriptions for all drugs paid for in cash to understanding of the costs associated with 16 determine whether any of those doctors were 16 criminal diversion, by patient diversion abuse, 17 17 and the other listed categories? involved in diversion? 18 18 MR. SNAPP: Object to the form. MR. SNAPP: Object to the form. 19 19 A. I don't know. A. Opioid X health economics. 20 20 (Witness reviewing document.) BY MR. STEWART: 21 21 BY MR. STEWART: Q. Now I'd like you to turn to the page, 22 and I tried to mark it, the page that shows risk 22 Q. I guess I should put this on the 23 23 factors. Do you see that? You have a page in screen. 24 this PowerPoint marked Exhibit 28 that's 24 A. Could you repeat the question? 25 25 entitled "Risk Factors"? O. Sure. Page 249 Page 247 A. Yes, I see it, sir. 1 1 Do you see on the document, now I've put it on the screen, if you look at the page 2 Q. And do you see it has financial, clinical, and personal risk factors? 3 3 that has a Bates number, which is the number at A. Yes, I do. 4 4 the bottom right-hand corner, that ends with 5 Q. Looking at all these risk factors, do 5 2047, do you see that page? 6 you know if Purdue, in following up on the 6 A. Yes, I do. 7 analysis that's presented in this PowerPoint, Q. Now, do you see, for example, there's 8 ever looked at these risk factors and applied a paragraph on this document that says "Costs 9 9 them to prescribers throughout the United States associated with criminal diversion," and it 10 10 to identify prescribers that might be involved lists a series of costs. 11 11 in diversion? Do you see that? 12 12 MR. SNAPP: Object to the form. A. Yes, I do. 13 13 Q. Does that look like something you A. I don't know. 14 BY MR. STEWART: 14 would have written to summarize the costs of 15 15 Q. I'd like to hand you a document and criminal diversion? 16 ask you if it's got the exhibit sticker 32 on 16 MR. SNAPP: Object to the form. 17 17 A. I don't know if I'm the sole author, it. 18 18 (Whereupon, Purdue-Wright-32 was but I probably contributed to it. 19 19 BY MR. STEWART: marked for identification.) 20 20 BY MR. STEWART: Q. That's consistent with your thinking? 21 Q. I've got copies for both counsel. 21 A. It is consistent with my thinking. Q. How about the list of "Costs 22 Do you see that document? 22 23 associated with By-patient diversion," similarly 23 A. Yes, I do. 24 Q. It's got Exhibit 32, a sticker on it 24 consistent with your thinking? 25 25 identifying it, fair? MR. SNAPP: Object to the form.

Page 250 Page 252 1 A. It is consistent with my thinking. A. With my guessing. I don't know what 2 BY MR. STEWART: percentage of pharmacy boards, state boards, 3 3 impaired professional programs are associated Q. Do you see that the second paragraph 4 of this statement says "Such costs cannot be with abuse and diversion, but I wrote them down 5 5 determined in controlled studies (too low as possibles. 6 6 BY MR. STEWART: frequency) but can be identified by 7 epidemiologic techniques and the fraction due to Q. I'd like to hand you another exhibit 8 an individual drug estimated." 8 which is marked Exhibit 33. 9 9 Do you see that? (Whereupon, Purdue-Wright-33 was 10 10 A. I see that. marked for identification.) 11 Q. Fair to say that's something you would 11 BY MR. STEWART: 12 12 agree with and have, in fact, said in other Q. Do you see you have Exhibit 33 in 13 13 front of you? contexts? 14 14 MR. SNAPP: Object to the form. A. I have Exhibit 33 in front of me. 15 15 A. In theory. I must confess that health Q. And can you turn to the first page and 16 economics is tricky, and I'm not sure I know how tell me whether you see it marked -- or the 17 to do that. But the way in which you would 17 second page of the exhibit, can you tell me 18 18 approach this kind of thing would be by that whether it's marked with a Bates number 0087? 19 19 way. A. It is so marked, sir. 20 20 BY MR. STEWART: Q. And do you see that this is a 21 21 Q. And I'd just like -- I'm going to get description of the RADARS system? to it, do you see the list, it's got "Costs 22 22 A. It's a description of the early 23 23 associated with abuse"? concept of the RADARS system. 24 A. Yes. 24 Q. Do you know if you wrote this 25 25 description? Q. Again similarly, is that consistent Page 251 Page 253 1 1 with your thinking, this list of costs A. I don't know if I solely authored it. 2 I suspect that the -- from the typeset and the associated with abuse --3 3 MR. SNAPP: Object to the form. way it's laid out that it looks like a Curt 4 4 Wright document. BY MR. STEWART: 5 5 Q. -- on the page marked 207? Q. Thank you. 6 MR. SNAPP: Object to the form. 6 (Whereupon, Purdue-Wright-34 was 7 7 A. Those are representative costs. I'm marked for identification.) 8 not sure they're complete. 8 BY MR. STEWART: 9 9 BY MR. STEWART: Q. I hand you Exhibit 34. And do you see 10 10 that that is a document that has been sent to Q. If we turn over to the page, 11 Exhibit 32 that has a Bates stamp that ends in 11 you by e-mail from a Dr. Sidney Schnoll? You're 12 12 2048. Do you see there's a statement "Costs on the fourth line down. 13 13 associated with addiction"? A. I see myself as a recipient on the 14 14 A. I do, sir. fourth line down. 15 15 Q. And can you just look at the document, Q. Again, do those costs that are listed 16 here, are they consistent with your view of 16 is this a document that was sent to you that 17 17 costs associated with addiction? contains a RADARS system executive summary? 18 18 MR. SNAPP: Object to the form. MR. PETRILLO: Just for the record, it 19 19 A. Yes, they are, sir. looks like the document was sent originally by 20 20 BY MR. STEWART: Brianne Weingarten and then forwarded by an 21 Q. And finally, do you see there's a 21 Anthony Santopolo. It's a little different from 22 22 the way you described it, but I don't think --"Costs associated with misuse/abuse/addiction," 23 23 and you've got a final list, is that consistent MR. STEWART: I see that's the way it 24 with your understanding? 24 was copied. Let me strike that. 25 MR. SNAPP: Object to the form. 25 BY MR. STEWART:

Page 254 1 Q. Do you see this is a document that was published as part of a NIDA Research Monograph 2 2 sent from Anthony Santopolo to you and others? early next year." 3 3 Do you see that? A. That is what I see. 4 4 Q. Initially I mischaracterized it. A. Yes. 5 5 Do you see that what Mr. Santopolo has Q. Does that refresh your recollection 6 done has sent you a RADARS System executive 6 that he was contacting you to get a summary of 7 your presentation so he could put it in a summary? 8 A. It looks like it. publication? 9 9 Q. Do you recall getting an executive A. It is what it says. summary of the RADARS System while you were at 10 10 Q. And can you turn to the page of this 11 Purdue? 11 document, this exhibit which is Exhibit 35, that 12 12 A. I don't remember this. ends -- that has a Bates stamp ending in 4827? 13 13 Q. Is it fair to say that the RADARS Do you see that? 14 system is something you became familiar with at 14 A. Yes. 15 15 Purdue? Q. Do you see it's got your name with a 16 MR. SNAPP: Object to the form. 16 colon, and it's got a series of comments? 17 17 A. It is fair to say that I knew about A. Yes. 18 18 RADARS when I was at Purdue. Q. And if you want to look at it for a 19 BY MR. STEWART: 19 moment and tell me if you generally remember 20 20 presenting these comments. Q. And you have no reason to think you wouldn't have been sent these materials while 21 21 A. Well, I remember now because I 22 22 you were at Purdue? remember the title. 23 23 A. I would have no reason to dispute. (Witness reviewing document.) 24 (Whereupon, Purdue-Wright-35 was 24 Q. I've highlighted a portion, sir, and 25 marked for identification.) you can see it on the board, which is the second Page 255 Page 257 paragraph, and it starts with the word "Most." 1 BY MR. STEWART: 2 I wondered if you could read those first two Q. I'm going to hand you Exhibit 35. Do 3 3 you see that you've got in front of you an sentences into the record. 4 e-mail to you, looks like from a person named 4 A. Sure. "Most physicians agree that 5 Schmidt? iatrogenic addiction is an uncommon event in the 6 A. Yes. clinical management of acute pain states, with 7 7 Q. Do you see it is entitled "CPDD an incidence of perhaps 1 in 10,000 patients 8 Symposium Publication"? 8 treated. Being so uncommon, it is assumed to 9 9 A. Yes. represent a negligible risk. This is a grave 10 Q. And are you familiar with this 10 error. Iatrogenic addiction ceases to be a rare 11 11 and negligible problem as soon as the size of publication? 12 12 A. Well, CPDD is the College on Problem the acute opioid analgesic market is taken into 13 of Drug Dependence, and they have a variety of 13 account." 14 venues in which publications are presented. 14 Q. Is that something that you would have 15 15 Q. Do you recall providing materials to stated at a symposium like this? 16 CPDD relating to your discussions at a 16 A. Yes. 17 17 symposium? Q. And is this consistent with your views 18 A. I remember Bill Schmidt wanting 18 even today? 19 19 something. I don't -- I'm not real clear on A. Yes. 20 20 what I did. MR. SNAPP: Object to the form. 21 21 BY MR. STEWART: Q. Do you see that he says "Thanks to 22 22 everyone who submitted a summary of their Q. Have you looked at studies in recent 23 presentation to be included in the summary of 23 years analyzing the correlation between treatment with long-term opioid therapy and 24 our symposium on 'New Approaches to 24

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abuse and addiction?

Non-Addictive Analgesics.' This will be

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	giry confraencial - Subject to	<del>-</del> -	
	Page 258		Page 260
1	A. No.	1	symposium starting with the words "There are
2	Q. So you haven't analyzed whether or not	2	about."
3	more recent studies have determined that there's	3	A. I lost it.
4	a much higher risk of abuse and addiction?	4	Q. It's right after the pink highlight on
5	MR. SNAPP: Object to the form.	5	the materials that I gave you.
6	A. I don't know what the recent studies	6	MR. SNAPP: Object to the form.
7	show.	7	A. "There are about 130 million
8	BY MR. STEWART:	8	prescriptions written for oral medications
9	Q. We just have to ask someone else about	9	containing oxycodone, hydrocodone, hydromorphone
10	that?	10	and propoxyphene every year. If even 1 in
11	A. You have to ask somebody else about	11	10,000 patients (1 in 10,000) a year develops
12	that.	12	de novo addiction as the result of such
13	Q. What you were saying here is, look,	13	treatment, this means 13,000 new addicts" per
14	even if you assume that the risk per human is	14	year.
15	quite low, the risk for all patients being		BY MR. STEWART:
16	treated with opioids leads to a significant	16 17	Q. I take it that's the statement you
17	number?	18	made to the symposium and allowed to be
18 19	A. Number.	19	published?
20	Q. Is that fair?	20	MR. SNAPP: Object to the form.
21	MR. SNAPP: Object to the form.	21	A. Yes. BY MR. STEWART:
22	A. I agree that if you have a large	22	Q. You're not backing away from that
23	denominator, even a low risk means a large number of people.	23	statement?
24	BY MR. STEWART:	24	A. I'm just saying that those were
25	Q. And do you see here that you identify	25	theoretical numbers, that I took the best
			theoretical named by that I took the best
	Page 259		Page 261
1	in your talk the significant denominator by	1	numbers I had at the time. Those numbers
2	in your talk the significant denominator by saying "There are about 130 million	2	numbers I had at the time. Those numbers certainly have probably changed.
2 3	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications	2 3	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really
2 3 4	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone	2 3 4	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best
2 3 4 5	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?	2 3 4 5	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?
2 3 4 5 6	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene.	2 3 4 5 6	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.
2 3 4 5 6 7	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene.  Q. Thank you.	2 3 4 5 6	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph
2 3 4 5 6 7 8	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene.  Q. Thank you.  And the point is you point out, am I	2 3 4 5 6 7 8	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about
2 3 4 5 6 7 8	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene. Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you	2 3 4 5 6 7 8	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two
2 3 4 5 6 7 8 9	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene.  Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new	2 3 4 5 6 7 8 9	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.
2 3 4 5 6 7 8 9 10	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene. Q. Thank you. And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?	2 3 4 5 6 7 8 9 10	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a
2 3 4 5 6 7 8 9	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene. Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?  MR. SNAPP: Object to the form.	2 3 4 5 6 7 8 9	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a stranger in a bar will pay for a tablet) of
2 3 4 5 6 7 8 9 10 11	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene.  Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?  MR. SNAPP: Object to the form.  A. Given those numbers in that	2 3 4 5 6 7 8 9 10 11	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a stranger in a bar will pay for a tablet) of diverted opioids is substantial, ranging from \$1
2 3 4 5 6 7 8 9 10 11 12	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene. Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?  MR. SNAPP: Object to the form.	2 3 4 5 6 7 8 9 10 11 12	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a stranger in a bar will pay for a tablet) of diverted opioids is substantial, ranging from \$1 up to \$20 per tablet (prices vary depending on
2 3 4 5 6 7 8 9 10 11 12 13	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene. Q. Thank you. And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?  MR. SNAPP: Object to the form. A. Given those numbers in that hypothesis, yes. The problem is I don't know if	2 3 4 5 6 7 8 9 10 11 12 13	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a stranger in a bar will pay for a tablet) of diverted opioids is substantial, ranging from \$1 up to \$20 per tablet (prices vary depending on the strength, desirability, and the current
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene.  Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?  MR. SNAPP: Object to the form.  A. Given those numbers in that hypothesis, yes. The problem is I don't know if it's true.  BY MR. STEWART:	2 3 4 5 6 7 8 9 10 11 12 13 14 15	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a stranger in a bar will pay for a tablet) of diverted opioids is substantial, ranging from \$1 up to \$20 per tablet (prices vary depending on the strength, desirability, and the current supply). Given that the cost of most common opioid analgesics is less than \$0.50 a tablet,
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene. Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?  MR. SNAPP: Object to the form.  A. Given those numbers in that hypothesis, yes. The problem is I don't know if it's true.  BY MR. STEWART: Q. You say you don't know if it's true.  Why do you say that?  A. The whole the paragraph says if it's this rate and you have this many people you could have you could potentially have this many addicts or abusers. To make that useful you need to have some idea of the numbers.  Q. And let me just ask you to read into	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a stranger in a bar will pay for a tablet) of diverted opioids is substantial, ranging from \$1 up to \$20 per tablet (prices vary depending on the strength, desirability, and the current supply). Given that the cost of most common opioid analgesics is less than \$0.50 a tablet, there is substantial profit in diversion and resale, at all levels (manufacturer, wholesaler, retail pharmacy, physician and patient)."  Q. And this is what you presented at the symposium, fair?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	in your talk the significant denominator by saying "There are about 130 million prescriptions written for oral medications containing oxycodone, hydrocodone, hydromorphone and propoxyphene every year"?  A. Propoxyphene.  Q. Thank you.  And the point is you point out, am I correct, that given that huge denominator you have a significant risk of thousands of new addicts each year?  MR. SNAPP: Object to the form.  A. Given those numbers in that hypothesis, yes. The problem is I don't know if it's true.  BY MR. STEWART:  Q. You say you don't know if it's true.  Why do you say that?  A. The whole the paragraph says if it's this rate and you have this many people you could have you could potentially have this many addicts or abusers. To make that useful you need to have some idea of the numbers.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	numbers I had at the time. Those numbers certainly have probably changed.  Q. Okay. Point is they're not really theoretical numbers so much you took the best numbers you had at the time, fair?  A. Fair.  Q. Do you see on the fourth paragraph down there's a statement that you make about street value? I'd ask you to read the first two sentences of that paragraph into the record.  A. "The street value (the amount a stranger in a bar will pay for a tablet) of diverted opioids is substantial, ranging from \$1 up to \$20 per tablet (prices vary depending on the strength, desirability, and the current supply). Given that the cost of most common opioid analgesics is less than \$0.50 a tablet, there is substantial profit in diversion and resale, at all levels (manufacturer, wholesaler, retail pharmacy, physician and patient)."  Q. And this is what you presented at the symposium, fair?  MR. SNAPP: Object to the form.

Page 262 Page 264 1 Q. And actually, you've stated this in 1 to proper uses of OxyContin? many different ways we've read today, you've 2 2 MR. SNAPP: Object to the form. 3 warned of your concern that these opioids like 3 A. That would have been a function in the 4 OxyContin have a significant street value and 4 marketing department. 5 are subject to diversion? 5 BY MR. STEWART: 6 MR. SNAPP: Object to the form. 6 Q. More broadly, do you remember earlier 7 A. I have said that multiple times today. 7 today you testified that the FDA found that 8 8 BY MR. STEWART: OxyContin, it wasn't any better than the 9 9 Q. Now, we're talking about iatrogenic existing opioid therapy, except that it had a 10 10 addiction. I'm curious, do you remember different dosing, fair? 11 testifying earlier today that when you were at 11 MR. SNAPP: Object to the form. 12 12 A. Not quite right. That the clinical the FDA you made it clear you did not want to 13 13 see OxyContin indicated for osteoarthritis? trials that were submitted showed no competitive 14 14 MR. SNAPP: Object to the form. superiority to immediate-release oxycodone. 15 15 BY MR. STEWART: A. I did not want to see OxyContin 16 indicated for osteoarthritis. 16 Q. Did you ever, when you went to Purdue, 17 17 take any steps to determine whether or not BY MR. STEWART: 18 18 Q. Did the FDA ever change its position Purdue's sales force was marketing OxyContin in 19 19 on that, that you know of? ways that were inconsistent with your 20 20 A. I don't know what the FDA has done. determination at the FDA? 21 21 Q. Let me say it this way. While you A. No. I did not, sir. 22 were at Purdue still involved with opioids, did 22 Q. Is the reason the same that you gave 23 you ever become aware that the FDA had said it's 23 before, that you were working on other things? 24 fine to use OxyContin for osteoarthritis? Did 24 MR. SNAPP: Object to the form. 25 the FDA -- strike that. Start a new question. 25 A. The same reason, I was fully occupied Page 263 Page 265 Did the FDA, while you were at Purdue, with the duties that I'd been assigned. 1 1 2 2 ever tell Purdue it is okay to say that BY MR. STEWART: 3 3 OxyContin is indicated for osteoarthritis? Q. I'm going to hand you Exhibit 36. 4 MR. SNAPP: Object to the form. 4 (Whereupon, Purdue-Wright-36 was 5 A. I have no idea. 5 marked for identification.) 6 BY MR. STEWART: 6 BY MR. STEWART: 7 7 Q. That wasn't in your area of concern at Q. And I'd like, sir, to ask you if you 8 Purdue? 8 recognize this. 9 9 MR. SNAPP: Object to the form. (Witness reviewing document.) 10 A. I might have considered it in my area 10 A. I don't remember writing the document, 11 of concern, but that didn't mean I knew about 11 but it looks very much like a Curt Wright 12 12 document. 13 13 BY MR. STEWART: Q. And do you see that on the front of 14 Q. Let me ask you this. When you were at 14 the document that is Exhibit 36 you've got a 15 15 Purdue, did you ever check to see whether Purdue page that's marked 4640, that's the last four 16 salespeople were, in fact, promoting OxyContin 16 digits of the Bates number? 17 17 for osteoarthritis? A. Yes. 18 18 A. No. Q. It's the very front. 19 19 Q. Why not? MR. PETRILLO: Front page. Have you 20 A. I had three drug development programs 20 got it? 21 to run, and I was busier than could be. I 21 BY MR. STEWART: 22 didn't have time for looking at anything else. 22 Q. Do you see -- by the way, we've talked 23 23 Q. Who was the person at Purdue, if you about Bates numbers, just so the record is clear

24

25

know, who would have been in charge of analyzing

what salespeople were representing with respect

24

25

I take it you understand that a Bates number is

this number that's at the bottom right-hand

Page 266 Page 268 1 corner that we use to indicate what page we're BY MR. STEWART: 2 2 on? Do you see that? Q. Why do you think that's -- why was 3 3 that your prediction of the position the FDA A. Yes. 4 would take? 4 Q. That's what a Bates number is, right? 5 A. Mm-hmm. 5 MR. SNAPP: Object to the form. 6 6 A. Earlier today I talked about a paper Q. So here we're at Bates number 4640. 7 7 that we did that looked -- that said the more Do you see that this document was sent from you 8 to Mr. Santopolo? drugs in the pipeline, the more diversion you're 9 A. Yes, I do. 9 going to get. I was very proud of that paper 10 10 Q. Okay. And it looks like materials because Nab Dasgupta was finally to prove -- was 11 that you prepared to get Purdue ready for its 11 able to prove something that I believed to be 12 OxyContin FDA negotiations. 12 true. I believed this to be true, the more 13 13 people are -- and I think other people at the Do you see that? 14 14 A. Yeah, I'm not sure about that. FDA believed it, too, the more drug is being 15 15 O. Okav. used the more diversion you're going to have. 16 A. I said earlier today that people would 16 That's what I said. 17 17 ask me questions, they'd say what would likely Q. But what you recommended Purdue's 18 18 happen if -- about this or about that or about position would be -- or strike that. 19 19 the other. I don't know if this represents my What you warn is that the FDA, because 20 20 advising Tony on specific negotiations or of that causal linkage between prescribing and 21 21 writing another thought piece as to what could diversion, would restrict promotion to oncologic 22 22 usage? happen. 23 23 Q. Do you see, if you turn to Page 4641, A. It could do that. 24 that the heading of the document is entitled 24 MR. SNAPP: Object to the form. 25 "OxyContin FDA Negotiations Issues Document"? BY MR. STEWART: Page 267 Page 269 A. Yes. 1 1 Q. The FDA warning could say, look, we're 2 Q. And do you see that the way this just going to let OxyContin be a cancer drug, 3 document is broken out is you list the FDA --3 not a general use drug, fair? 4 4 for a series of issues you list the FDA MR. SNAPP: Object to the form. 5 unilateral position worst, and then Purdue's 5 A. That is what that sentence says. 6 position best, and then you predict an outcome? 6 BY MR. STEWART: 7 A. Yes, I do. Q. And you're proposing that Purdue, 8 though, urge a different tack, which is merely Q. And do you see that, for example, on 9 9 the Page 4642 there's a section on advertising? modification of promotion material to promote 10 10 A. Yes, I do. OxyContin as a WHO step two drug along with 11 Q. And do you see that you warn that "The 11 provision of non-product specific materials on 12 12 agency will take the position that part of the control of misuse, abuse, and diversion, fair? 13 13 problem with diversion is due to an MR. SNAPP: Object to the form. 14 inappropriately large denominator of usage due 14 A. I'm not sure that's what I'm 15 15 to promotion of the drug for the management of advocating, but I'm saying that's what could be 16 non-malignant pain"? Do you see that? 16 done. 17 17 A. I see that. BY MR. STEWART: 18 18 Q. Is what you're warning there, you're Q. Okay. And do you know what was done 19 19 with these materials that you provided? saying the FDA will say one of the problems is 20 that OxyContin is being prescribed for too broad 20 A. I have no idea. 21 a series of conditions and that is leading to 21 Q. Was there anyone at Purdue at the time 22 22 diversion, isn't that how you're articulating this document that is Exhibit 36 was written 23 23 the challenge by the FDA? that had better knowledge of the inner workings 24 MR. SNAPP: Object to the form. 24 of the FDA --25 25 A. Yes, I am, sir. MR. SNAPP: Object to the form.

Page 270 1 BY MR. STEWART: notified of a meeting that you had to go to, was 2 2 Q. -- than you? that by e-mail typically? 3 MR. SNAPP: Object to the form. 3 A. I believe it was almost always by 4 4 A. You're asking two questions, and e-mail. 5 5 they're difficult because after I left the FDA Q. Do you remember attending meetings 6 there were large, large changes in the division, 6 with Purdue, other Purdue employees to 7 strategize about an OxyContin abuse diversion and the new -- I already knew that the new 8 division director had different opinions than I 8 meeting coming up with the FDA? 9 did, so I could not be sure what they would do. 9 MR. SNAPP: Object to the form. 10 10 And I found that many 20-year experienced A. I don't know whether I did or not. I 11 regulatory affairs professionals in all 11 was for a brief period of time attending a 12 12 companies tended to be dismissive of my opinions couple of meetings on abuse and diversion, and 13 then Dave Haddox took over. So it's entirely 13 because they believed they knew their business 14 14 better than I. conceivable I could have, I just can't remember. 15 15 BY MR. STEWART: BY MR. STEWART: 16 Q. So it sound like you thought you 16 Q. Let me hand you a document marked 17 probably had the best understanding of the FDA 17 Exhibit 38. 18 within the company, but you felt like others 18 (Whereupon, Purdue-Wright-38 was 19 19 also felt like they had expertise, fair? marked for identification.) 20 20 A. That's fair. BY MR. STEWART: 21 Q. I'm going to hand you Exhibit 37. 21 Q. And do you recognize that as a 22 (Whereupon, Purdue-Wright-37 was 22 PowerPoint presentation that you sent 23 23 marked for identification.) Mr. Santopolo on March 30th, 2001? 24 BY MR. STEWART: 24 A. I certainly recognize it as a 25 25 Q. And I want you to look at it and tell PowerPoint presentation. I believe I authored Page 271 Page 273 me whether you recognize it. I'll tell you it it, I don't know if I was the sole author. And 1 2 may be two documents combined. Do you see the 2 the header says that I sent it on 3/30/2001. 3 3 page marked 7492 --Q. And turn to the first page of the 4 (Witness reviewing document.) 4 materials. Do you see that we have no page Q. -- which is the second page of the 5 5 numbers on these pages of this PowerPoint? 6 document after the cover page? 6 A. There are no page numbers. 7 7 A. Yes. Q. Okay. Well, if you'll -- I'm going to 8 8 refer to pages by the headings. Do you see that Q. Do you recognize that as an agenda for 9 OxyContin abuse diversion meeting? 9 if you turn to the first page there's a slide 10 A. That's what it's labeled. 10 entitled "The OxyContin Crisis"? 11 Q. Is that your writing on there, the 11 A. Yes. 12 12 handwriting? Q. And do you see that the center bullet 13 A. I don't think so. 13 point says "OxyContin has been reported as 14 Q. Okay. Do you know if you attended a 14 having a high rate of criminal misuse, abuse and 15 15 meeting about OxyContin abuse diversion in diversion"? 16 February of 2001? 16 A. Yes. 17 17 A. I don't know. Q. That wasn't controversial at this time 18 18 by the time this was distributed, fair? Q. At Purdue did you use a calendaring system like Outlook, something like that? 19 19 MR. SNAPP: Object to the form. A. I don't think so, but I can't 20 20 A. Not to me. 21 remember. 21 BY MR. STEWART: Q. Do you think your secretary kept a 22 22 Q. Can you turn to the next page of 23 paper calendar? 23 Exhibit 38, and tell me if you've arrived at a 24 A. I don't know what -- I don't know. 24 slide entitled "The OxyContin Crisis," the 25 25 Q. How were meetings -- how would you be second slide?

Page 274 Page 276 1 A. Yes. 1 Opioid X program. 2 2 Q. And is the middle bullet a bullet that Q. Can you turn to the page in Exhibit 38 3 3 that's entitled "What Has Been Done?" says "PPLP strongly believes that the public 4 will be best served if the company works in a 4 A. I have found that page. 5 responsible, proportional and coordinated manner 5 Q. Do you see that the third bullet says 6 with the appropriate governmental and 6 "This response must include appropriate 7 7 non-governmental agencies to bring a quick modifications to labeling, marketing, promotion, 8 8 resolution to the problem"? provider education and regulation, as well as 9 A. Yes. 9 modifications (if possible) to the actual dosage 10 10 Q. Was that the approach that Purdue took form"? 11 with the FDA, that it would be a cooperative 11 A. I see that, sir. 12 12 partner in addressing the diversion of Q. Are you describing here what Purdue 13 13 can do to address the outbreak of diversion of OxyContin? 14 14 MR. SNAPP: Object to the form. OxyContin? 15 15 A. My -- I do not remember this. I mean, A. I am describing what Purdue could do. 16 I remember something like this, but I do not 16 Q. Did you say that you're not familiar 17 remember the specifics. I believe this may be 17 with the guilty plea entered by Purdue and three 18 what I told Tony Santopolo what Purdue should 18 top executives in 2007 for misbranding 19 19 do. OxyContin? 20 20 BY MR. STEWART: A. I only know that it existed. 21 21 O. Do you know whether Purdue led the FDA Q. So we'd have to look at that guilty 22 to believe that it was going to work in a 22 plea to determine whether the actions in the 23 23 responsible, proportional and coordinated manner guilty plea are consistent with the response 24 with the FDA and other appropriate governmental 24 that you're suggesting, fair? 25 25 and non-governmental agencies to bring a quick MR. SNAPP: Object to the form. Page 275 Page 277 solution to the problem of diversion of A. I don't understand. 1 1 2 OxyContin? BY MR. STEWART: 3 3 MR. SNAPP: Object to the form. Q. Sure. 4 A. I was not on the OxyContin team, and I 4 To determine whether or not all the 5 actions that are listed in Purdue's guilty plea don't know. 6 BY MR. STEWART: are consistent with modifications to labeling, 7 7 marketing, promotion, and so forth to address Q. Can you turn until you find a page of 8 this PowerPoint that is Exhibit 38 that's 8 the diversion problem, we'd have to compare what 9 9 entitled "What could be done?" you're proposing to the guilty plea, fair? 10 10 A. I have found that page. MR. SNAPP: Object to the form. 11 11 A. I'm not sure the -- since I don't know Q. Okay. Do you see that the last bullet 12 12 says "Fortunately, PPLP" -- that is Purdue -what the guilty plea was --13 "has been preparing for this kind of problem 13 BY MR. STEWART: 14 ever since we first became aware of rumors of 14 Q. Fair enough. 15 15 OxyContin abuse"? Do you see that? A. -- I can't answer that one. 16 16 A. I see that. Q. I hand you Exhibit 39. 17 17 (Whereupon, Purdue-Wright-39 was O. What sort of preparation had Purdue 18 18 been doing? marked for identification.) 19 19 A. It first formed a committee. That was BY MR. STEWART: 20 the committee I attended that was very early. 20 Q. I'm going to hand you Exhibit 39. Do 21 It then hired, I believe new hired someone in --21 you have it? 22 22 whose expertise was diversion, criminal A. I have that. 23 diversion. It then hired Dr. Haddox. It then 23 Q. Do you see it's an "Agreed Statement 24 hired Dr. Schnoll. It then built my entire 24 of Fact," that's the title? Do you see that? 25 25 department. And it also put muscle behind the A. I see that.

	D 270	T	D 200
	Page 278		Page 280
1	Q. And I take it you're not familiar with	1	there's a page in Exhibit 38 entitled "What Can
2	this document?	2	The Sponsor Do"?
3	A. I am not familiar with this document.	3	A. Yes, there is.
4	Q. And I'll tell you what, can you turn	4	Q. And do you see on the second bullet
5	to Page 6 of 16? The pages on the document have	5	says Purdue PPLP in this presentation is
6	their own internal pagination. Do you see that?	6	Purdue, fair? Is that correct?
7	A. Yes.	7	A. PPLP is one acronym for Purdue.
8	Q. Do you see there's a subparagraph B?	8	Q. And you're saying "Purdue has to," and
9	A. Mm-hmm.	9	then you have a colon, and you list seven things
10	Q. I take it if Purdue sales	10	that should be done, is that correct?
11	representatives were telling healthcare	11	A. That is correct.
12	providers that OxyContin potentially creates	12	Q. And do you know if Purdue carried out
13	less chance for addiction than immediate-release	13	your recommendations with respect to these seven
14	opioids, that would not be marketing that would	14	items that are on Exhibit 38, the page entitled
15	help reduce diversion, fair?	15	what can the sponsors "What Can The Sponsor
16	MR. SNAPP: Object to the form.	16	Do?"
17	A. Okay. But I do need one piece of	17	MR. SNAPP: Object to the form.
18	information.	18	A. They carried to my knowledge, which
19	BY MR. STEWART:	19	is limited to where I was working and what I was
20	Q. Sure.	20	doing, they carried out a number of them.
21	A. When was this supposed to have	21	BY MR. STEWART:
22	happened?	22	Q. Let me ask you, today as you look at
23	Q. And I'll just tell you, if this	23	this, do you still believe that your list of
24	happened in the period that you're creating this	24	items, things that should be done to reduce
25	PowerPoint, that would be inconsistent in 2001	25	diversion of OxyContin, was a good list? Was
	Page 279		Page 281
1	with what you're suggesting, fair?	1	this the list of things that Purdue should have
2	MR. SNAPP: Object to the form.	2	done?
3	A. It would be inconsistent in my	3	MR. SNAPP: Object to the form.
4	PowerPoints, speaking as somebody in the abuse	4	A. I believe that is a list of things
5	of the group that was concerned passionately	5	that should have been done.
6	with abuse, I made a number of suggests that	6	BY MR. STEWART:
7	Purdue should do, and I'm aware that it will	7	Q. Okay. Can you turn to a page
8	take a certain amount of time to implement it,	8	entitled a page of Exhibit 38 entitled
9	to agree to a suggestion, then implement a	9	"Modify the marketing of our products"? Do you
10	suggestion. So I simply don't know what time	10	see that?
11	period we're talking about.	11	A. Modify the labeling of such products
12	If had someone asked me do you	12	to aid the prescriber.
13	think we're these are adequate changes to	13	Q. I'm looking at something that says
14	deal with abuse and diversion, changes in the	14	"Modify the marketing of our products (to center
15	label, changes in the detailing materials, I	15	on appropriate patient selection)."
16	would have looked at that. I'm not happy today	16	Do you see that?
17	that if these agreed if this is a statement	17	A. I see that.
18	of fact and they were telling people that this	18	Q. Do you see the second bullet says
19	has less abuse potential than immediate-release	19	"PPLP" Purdue "could do more to encourage
20	opioids, I'm not happy that they were doing	20	proper usage and discourage misuse of our
21	that.	21	products."
22	Q. Turning back to Exhibit 38, which is	22	Do you see that?
	Q. Turning odek to Lamoit 30, which is		Do you see mat:

24

Q. Do you see that? Do you see that

this PowerPoint.

A. Yes.

23

24

25

Q. What was your belief, what were they

not doing that Purdue needed to do more of?

	Page 282		Page 284
1	A. I thought they were marketing with	1	want to dial back and use a drug that's less
2	respect to the label. I thought they needed to	2	susceptible to diversion, fair?
3	market in a more stringent way.	3	MR. SNAPP: Object to the form.
4	Q. And where did you have the impression	4	A. If you're in a hotspot and things are
5	that more stringent marketing methods were	5	going badly, you want to change what you're
6	needed?	6	prescribing.
7	MR. SNAPP: Object to the form.	7	BY MR. STEWART:
8	A. Because that's what you do. I mean,	8	Q. I hand you an exhibit marked
9	just believed at the time that that's what would	9	Exhibit 40.
10	help.	10	(Whereupon, Purdue-Wright-40 was
11	BY MR. STEWART:	11	marked for identification.)
12	Q. And I guess what I'm getting at is, it	12	BY MR. STEWART:
13	sounds like you had information that Purdue was	13	Q. I'd ask you to tell me if you
14	not doing enough to encourage proper usage and	14	recognize that document.
15	discourage misuse of our products. Am I reading	15	A. This appears to be a Regulatory Agency
16	that correctly?	16	Contact Report of a conversation with
17	MR. SNAPP: Object to the form.	17	Dr. Cynthia McCormick, division director of my
18	A. I did not have such information, I	18	old division.
19	don't think.	19	Q. And do you recall whether or not you
20	BY MR. STEWART:	20	were made aware at the time of this contact?
21		21	
22	<ul><li>Q. So this was a surmise in your mind?</li><li>A. This was a surmise.</li></ul>	22	And I'll point out that you're copied on this
23		23	document on the next page which is marked 6255 with a Bates number.
24	Q. Can you turn now finally to a page	24	
25	entitled "Integrated Risk Management"? Do you	25	(Witness reviewing document.)
25	see that?	25	Q. Do you remember that?
	Da == 202		
	Page 283		Page 285
1	A. I have it.	1	Page 285  A. I don't remember this document.
1 2	_	1 2	_
	A. I have it.		A. I don't remember this document.
2	<ul><li>A. I have it.</li><li>Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page</li></ul>	2	<ul><li>A. I don't remember this document.</li><li>Q. Okay. Do you remember hearing</li></ul>
2 3	<ul><li>A. I have it.</li><li>Q. Do you see again we're on the exhibit</li></ul>	2	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started"
2 3 4	A. I have it. Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?	2 3 4	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the
2 3 4 5	A. I have it. Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.	2 3 4 5	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating
2 3 4 5 6	A. I have it. Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right. A. I think I'm in the right place.	2 3 4 5 6	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press
2 3 4 5 6 7	A. I have it. Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right. A. I think I'm in the right place. BY MR. STEWART:	2 3 4 5 6	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by
2 3 4 5 6 7 8	A. I have it. Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right. A. I think I'm in the right place. BY MR. STEWART: Q. And do you see the third bullet says	2 3 4 5 6 7 8	A. I don't remember this document.  Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."
2 3 4 5 6 7 8	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient	2 3 4 5 6 7 8	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by
2 3 4 5 6 7 8 9	A. I have it. Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right. A. I think I'm in the right place. BY MR. STEWART: Q. And do you see the third bullet says	2 3 4 5 6 7 8 9	A. I don't remember this document.  Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes.
2 3 4 5 6 7 8 9 10	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient turnover, increased geographic or regional risk, unusual volume of narcotic use or other risk	2 3 4 5 6 7 8 9 10	A. I don't remember this document.  Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes.  Q. And do you see then that on the fourth
2 3 4 5 6 7 8 9 10 11	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient turnover, increased geographic or regional risk, unusual volume of narcotic use or other risk factors, it is safer for the provider to use	2 3 4 5 6 7 8 9 10 11	A. I don't remember this document.  Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes.  Q. And do you see then that on the fourth paragraph down, or third I should say,
2 3 4 5 6 7 8 9 10 11 12	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient turnover, increased geographic or regional risk, unusual volume of narcotic use or other risk factors, it is safer for the provider to use narrow-spectrum, low diversion risk, or	2 3 4 5 6 7 8 9 10 11 12	A. I don't remember this document.  Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes.  Q. And do you see then that on the fourth paragraph down, or third I should say, Dr. McCormick says, or the document recounts,
2 3 4 5 6 7 8 9 10 11 12 13	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient turnover, increased geographic or regional risk, unusual volume of narcotic use or other risk factors, it is safer for the provider to use narrow-spectrum, low diversion risk, or tamper-resistant medications."	2 3 4 5 6 7 8 9 10 11 12 13	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes. Q. And do you see then that on the fourth paragraph down, or third I should say, Dr. McCormick says, or the document recounts, "Dr. McCormick stated that she felt the issues
2 3 4 5 6 7 8 9 10 11 12 13 14	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient turnover, increased geographic or regional risk, unusual volume of narcotic use or other risk factors, it is safer for the provider to use narrow-spectrum, low diversion risk, or tamper-resistant medications."  Do you see that?	2 3 4 5 6 7 8 9 10 11 12 13 14	A. I don't remember this document.  Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes.  Q. And do you see then that on the fourth paragraph down, or third I should say, Dr. McCormick says, or the document recounts, "Dr. McCormick stated that she felt the issues discussed at the April 23 meeting were much more
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient turnover, increased geographic or regional risk, unusual volume of narcotic use or other risk factors, it is safer for the provider to use narrow-spectrum, low diversion risk, or tamper-resistant medications."  Do you see that?  A. I see that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes. Q. And do you see then that on the fourth paragraph down, or third I should say, Dr. McCormick says, or the document recounts, "Dr. McCormick stated that she felt the issues discussed at the April 23 meeting were much more serious than what was written in the press
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I have it.  Q. Do you see again we're on the exhibit that is Exhibit 38, and now we're on a page entitled "Integrated Risk Management"? Do you see that?  MR. PETRILLO: Yes, right.  A. I think I'm in the right place.  BY MR. STEWART:  Q. And do you see the third bullet says "In settings where there is high patient turnover, increased geographic or regional risk, unusual volume of narcotic use or other risk factors, it is safer for the provider to use narrow-spectrum, low diversion risk, or tamper-resistant medications."  Do you see that?  A. I see that.  Q. So at that time that you produced this, OxyContin was not a narrow-spectrum, low diversion risk, or tamper-resistant medication, fair?  A. That is true.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I don't remember this document. Q. Okay. Do you remember hearing about do you see that the document states on the first page that "Dr. McCormick started out" and I've got it highlighted here on the screen "started out the discussion by stating that she was concerned about a recent press release (Attachment 1) that had been received by the Agency's press office for review."  Do you see that?  A. Yes. Q. And do you see then that on the fourth paragraph down, or third I should say, Dr. McCormick says, or the document recounts, "Dr. McCormick stated that she felt the issues discussed at the April 23 meeting were much more serious than what was written in the press release; in particular, that we did not talk about the problems specifically relating to OxyContin, rather, that it only addressed prescription drugs in general."  Do you see that?

	gilly conflidential - Subject to		
	Page 286		Page 288
1	Q. All you can do is identify this as a	1	A. I think he means the original package
2	document that you would have received a copy of,	2	insert for OxyContin.
3	is that fair?	3	Q. And he's saying you all were all
4	MR. SNAPP: Object to the form.	4	involved in that process, fair?
5	A. Yeah.	5	A. Yeah.
6	BY MR. STEWART:	6	Q. And that's accurate?
7	Q. I'm going to hand you a document	7	A. I was with the Food and Drug
8	marked Exhibit 41.	8	Administration, I reviewed it.
9	(Whereupon, Purdue-Wright-41 was	9	Q. And who are Robert, Bob, and Mike that
10	marked for identification.)	10	he's referring to?
11	BY MR. STEWART:	11	A. Robert would be Robert Reder. Mike
12	Q. I'd like to know if you recognize this	12	would be Mike Inn I'm not sure how to spell
13	document as an e-mail sequence.	13	his name.
14	(Witness reviewing document.)	14	Q. What role did he play?
15	Q. And I direct your attention, in fact,	15	A. I don't remember.
16	that your name comes up in the second e-mail	16	Q. Okay. And Bob?
17	down on the page marked 1719 of Exhibit 41.	17	A. Bob Kaiko.
18	Do you see that?	18	Q. Okay. And Dr. Sackler himself was
19	A. Mm-hmm.	19	involved in that process with respect to the
20	Q. Do you see where Dr. Richard Sackler	20	original package insert?
21	says, "Robert, Bob, Mike, I, and Curtis Wright	21	MR. SNAPP: Object to the form.
22	were all involved in the past and had a lot to	22	A. It says it here. I don't know.
23	do with the quality of the PI. It would be good	23	BY MR. STEWART:
24	for their knowledge to be tapped for this, the	24	Q. Did you ever have conversations with
25	most critical rewrite that we have ever had."	25	Dr. Sackler himself when you were at the FDA
	D 207		•
1	Page 287		Page 289
1	Do you see that?	1	regarding the package insert?
2	A. Mm-hmm.	2	A. No.
3	Q. Who is Richard Sackler?	3	Q. I hand you Exhibit 42.
4	A. Richard Sackler is one of the owners	4	(Whereupon, Purdue-Wright-42 was
5	of the company.	5	marked for identification.)
6	Q. And at this time did he have an	6	BY MR. STEWART:
7	official position?	7	Q. Sir, I hand you an exhibit and ask you
8	A. I'm not I'm not sure what his	8	if you recognize it.
9	position was at that time.	9	(Witness reviewing document.)
10	Q. I take it you've talked with Richard	10	A. I do not remember specifically writing
11	Sackler a number of times, fair?	11	the document. It is almost certainly my
12	MR. SNAPP: Object to the form.	12	authorship, and it looks like a thought piece I
13	A. A couple of times.	13	wrote for Sally Riddle.
14	BY MR. STEWART:	14	Q. And do you know if it was ever
15	Q. He sent you e-mails on subjects	15	published?
16	related to Purdue at different times?	16	A. I don't think it was ever published.
17	MR. SNAPP: Object to the form.	17	Q. And do you remember writing this
18	A. I'm not so sure. I don't know if he	18	thought piece?
19	sent me e-mails.	19	A. I remember thinking these thoughts. I
20	BY MR. STEWART:	20	didn't remember the thought piece until I looked
21	Q. Do you know what he's talking about	21	at it.
22	here when he says "Robert, Bob, Mike, I and	22	Q. Tell me about the tipping point. What
23	Curtis Wright were all involved in the past and	23	is the tipping point that you were referring to
24	had a lot to do with the quality of the PI"? Do	24	in this article?
25	you know what's he's referring to?	25	MR. SNAPP: Object to the form.
24	had a lot to do with the quality of the PI"? Do	24	in this article?

Page 290 1 A. The way I describe it in this article 1 Q. And can we assume that this is a 2 is that economic forces drive diversion of thought piece that you sent on June the 10th, 3 pharmaceuticals. Diversion of pharmaceuticals 3 2003 to all the various folks that are on this 4 results in their being used for abuse and e-mail chain, including Dr. Haddox? 5 diversion -- I mean, used for abuse. As cases 5 A. Haddox, Schnoll, Kramer, Douglas 6 of abuse grow, you eventually reach a tipping 6 Kramer, Alton Kremer, Lynn, yeah, I assume I 7 7 point where it becomes a crisis and you have to sent it to them. 8 do something immediately to try to control the 8 Q. I'm going to hand you another document 9 9 crisis. marked Exhibit 44. 10 10 (Whereupon, Purdue-Wright-44 was BY MR. STEWART: 11 Q. And what characterizes the tipping 11 marked for identification.) 12 12 BY MR. STEWART: point? 13 13 Q. And ask you if you recognize it as a A. Well, I've forgotten. The tipping 14 14 point, as I describe it here, if I am correct, deposition transcript of a deposition taken of 15 15 is when diversion and abuse have resulted in you in February, 2013. 16 enough cases so there is sufficient media 16 (Witness reviewing document.) 17 17 attention, publicity, press reports, internet A. It's what it's so labeled. 18 18 traffic, peer-to-peer communication so that the Q. Do you remember giving a deposition on 19 abuse of the drug explodes. 19 February the 13th, 2013? 20 20 A. I remember giving several depositions, Q. I think you've stated that today we 21 21 but I don't remember much of them. continue to be in a period of our national 22 22 Q. Any reason to think that you, looking history where the abuse of opioids is a major 23 23 social problem, fair? at this document -- well, I'll ask you this. 24 A. Every opioid, yes. 24 Looking at this document, does it 25 25 Q. When did -- when was the tipping refresh your recollection that, in fact, on Page 291 Page 293 point, in your mind, reached for this current February 13th, 2013 you gave deposition 1 2 cycle of abuse and diversion of opioids in the 2 testimony? 3 3 **United States?** A. I still don't know which one it was, 4 4 MR. SNAPP: Object to the form. but I can't -- there's no reason to dispute the 5 A. Can I look up one of my publications? record. 6 BY MR. STEWART: Q. And I take it if you testified in a 7 deposition, we can assume that you tried to O. Certainly. 8 8 testify accurately and truthfully? A. If I can find it. I haven't thought 9 9 about this in years. A. I have always tried to testify 10 10 (Witness reviewing document.) accurately. 11 A. I would say between 2000 and 2002. 11 Q. And that would be true for this 12 12 Q. And you've talked about opioids deposition, the transcript of which we have as 13 13 generally. That would certainly include Exhibit 44, fair? 14 OxyContin, fair? 14 A. I was sworn under oath, so I told the 15 15 A. Fair. best truth I knew. 16 16 Q. I'd just like to ask you about one Q. I'm going to hand you an exhibit, 17 17 page in the deposition. Could you turn to Exhibit 43. 18 18 (Whereupon, Purdue-Wright-43 was 19 19 marked for identification.) MR. PETRILLO: It may not matter, 20 20 BY MR. STEWART: Counselor, but are you representing you have all 21 Q. I'd like to know if you recognize this 21 the pages of the transcript in this exhibit? 22 MR. STEWART: Yes. If there's a 22 document.

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24

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believe.

Curt Wright.

(Witness reviewing document.)

A. It looks like another thought piece by

23

24

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missing page, we'll be happy to replace it.

A. I found Page 181 of the transcript, I

Page 294 Page 296 1 BY MR. STEWART: were characterizing in 2013 deposition, when you 2 2 were saying "if an abuser wants to take, wants Q. Do you see that you state -- you're 3 3 to get high, they can take an intact dosage form looking at a document, but you state, and I 4 don't have that document for you, that, and this of high enough strength, if they can get it, to 5 is the second paragraph down, "the problem that get high without having to crush the product at 6 6 all," you do believe that's correct? if an abuser wants to take, wants to get high, 7 7 they can take an intact dosage form of a high A. That is true. 8 enough strength, if they can get it, to get high 8 MR. SNAPP: Object to the form. 9 9 without having to crush the product at all." BY MR. STEWART: 10 10 Do you see that? Q. Okay. I'm going to hand you another 11 A. I see that. 11 document that I'll mark as Exhibit 45. 12 12 MR. PETRILLO: If we're going to go Q. Is it fair to say that's your view, 13 13 that's correct? for another half hour, maybe take a short break, 14 MR. SNAPP: Object to the form. 14 or do you think you're almost done? 15 15 A. I'm not sure it's my view anymore. MR. STEWART: No, I think we should 16 There have been events that have taken place 16 take a short break if you'd like. 17 17 since that time that suggest to me that it takes THE VIDEOGRAPHER: We are now going 18 18 less tamper-resistance than I thought to deter off the record, and the time is 5:49 p.m. 19 diversion and abuse of a particular dosage form. 19 (Whereupon, a recess was taken.) 20 20 THE VIDEOGRAPHER: We are now going BY MR. STEWART: 21 21 back on the record, and the time is 5:56 p.m. Q. I'm curious, what's brought you to 22 22 that belief? MR. PETRILLO: Can we start without 23 23 your colleague? A. After I left Purdue they changed the 24 formulation to something that approximated one MR. BENNER: We can start. 25 of the Opioid X formulations, and some years BY MR. STEWART: Page 297 Page 295 later I got an e-mail from a friend, and I don't Q. Dr. Wright, I'm going to hand you 1 1 2 remember who sent it to me, saying hey, look, it 2 Exhibit 45. 3 worked, and I saw that in that particular study 3 (Whereupon, Purdue-Wright-45 was 4 the new formulation had reduced overdose deaths 4 marked for identification.) 5 by 80 percent. BY MR. STEWART: 6 Q. Do you remember that study you're 6 Q. Do you recognize that exhibit as a 7 7 talking about? transcript of a deposition you gave on 8 8 A. I'm sorry, I don't. January 15th, 2014? And it's intended to be a 9 9 Q. And I take it -- we've talked a little complete transcript. 10 bit today about trends and diversion, those 10 (Witness reviewing document.) 11 11 sorts of things, but when you're providing this A. This looks like the deposition I gave 12 12 testimony right now you're not really basing it in Boston. 13 13 on the fact that you actually reviewed Q. And is it fair to say that when you 14 literature to suggest that there's a significant 14 gave this deposition, for which Exhibit 45 is 15 15 change, fair? In other words, you're not the transcript, that you tried to testify 16 suggesting -- you're mentioning an anecdote 16 truthfully and accurately? 17 17 about a communication with a friend? A. Yes, sir. 18 18 Q. Now I'm going to hand you deposition A. That --19 19 MR. SNAPP: Object to the form. excerpt 46. 20 20 A. -- cited a scientific paper that I (Whereupon, Purdue-Wright-46 was 21 then looked at and was impressed by the 21 marked for identification.) 22 reduction in overdose deaths. 22 BY MR. STEWART: 23 23 BY MR. STEWART: Q. This is not a transcript of your 24 Q. I guess what I'm getting at is, 24 deposition. It's a transcript of a deposition

25

by a Robert Reder.

though, first of all, you're not -- when you

25

Page 298 Page 300 1 Do you see that? BY MR. STEWART: 2 2 A. Excuse me, at the top it says that Q. Now, sir, we talked about -- and you 3 3 can set that exhibit aside. We talked about this contains confidential information. Is it 4 Richard Sackler. I think you identified him as proper for me to read this? 5 5 the owner of -- one of the owners of Purdue, Q. It is. 6 6 And do you -- can you identify Robert 7 7 MR. SNAPP: Object to the form. Reder? 8 8 A. Robert Reder was my superior at A. I do not know Dr. Richard's exact 9 Purdue. He was one of the leading physicians at title. He and the Sacklers -- the Sackler 10 10 Purdue Pharma, later left and went to Endo. family and that group of Sacklers owned the 11 Q. And can you tell me, I'm going to --11 company. 12 12 if you turn to Page 25 in the deposition, and BY MR. STEWART: 13 13 this is an excerpt, it's not the entire Q. Who are the Sacklers that you know of 14 14 transcript, do you see, and I've highlighted the that own the company? 15 15 material, that the deposition reads -- the MR. SNAPP: Object to the form. 16 question in part is "in December 1994, that no 16 A. Well, that's difficult because a 17 17 specific studies of the OxyContin formulation lawyer once told me that there's one guy in 18 18 had been conducted to ascertain if it had a Switzerland who knows how the companies are 19 19 lower abuse potential"? Do you see Dr. Reder organized, and he's never coming to the United 20 20 says "that's correct"? States. And I don't -- you're asking the wrong 21 A. I see that. 21 guy about the financial ownership of Purdue, the 22 Q. Do you agree with that? 22 Purdue-associated companies. 23 23 A. That's correct. BY MR. STEWART: 24 Q. Do you see then that there's a 24 Q. On the description, fair enough. 25 25 question, "Did Purdue ever do any specific I take it you don't know the name of Page 299 Page 301 studies to ascertain whether or not OxyContin the guy in Switzerland? 1 1 2 2 had a lower abuse potential than, say, A. No, I'm not sure he's in Switzerland. 3 morphine?" And he answers, "You 3 Q. Do you remember who told you that 4 mean...comparative studies?" The questioner 4 about this fellow in Switzerland? 5 says "Yes." And then he answers "No." 5 MR. SNAPP: Object to the form. 6 Do you see that? 6 To the extent -- you said it was a 7 7 A. Yes, I see that. lawyer. If it was a Purdue lawyer, I'm 8 8 instructing you not to answer on the grounds of Q. Do you share that view? 9 9 A. To the best of my knowledge, that's attorney/client privilege if it took place 10 10 during the time that you were at the company. 11 11 Q. Final question was in this deposition, BY MR. STEWART: 12 12 "What about immediate-release oxycodone Q. The only question I have for you to products?" And he answers "No." 13 13 explore that, and I don't want you ever to tell 14 14 Do you see that? me anything that you told a lawyer, but I take 15 15 A. Yes, I see that. it it is true that that was told to you by a 16 Q. Do you agree with that as well? 16 lawyer? Or now, let me step back for a minute. 17 17 MR. SNAPP: Object to the form. MR. STEWART: You've made your 18 18 A. I'd have to think about that one and objection, we can address it. I'll withdraw the 19 19 look at the data. And I simply cannot remember question. 20 20 because it was too long ago. I -- I'm not sure BY MR. STEWART: 21 there isn't data available. He is correct when 21 Q. Tell me, you mentioned two social 22 he says they did not do head-to-head abuse 22 occasions that you'd interacted with Richard 23 23 liability trials in post addicts, which are the Sackler, can you describe those social 24 conventional -- which is the standard, gold 24 occasions? 25 25 standard. MR. SNAPP: Object to the form.

Page 302 1 A. Well, they would have been at the just described, one more question about those 2 presentations which we made to the company and meetings. Were they annual meetings do you 3 to the family, and I said hello to him. think? 4 BY MR. STEWART: 4 A. I'm not sure. 5 5 Q. Tell me about that. What Q. Other than those meetings, have you 6 ever had a social meeting with any member of the presentations are you talking about? 7 Sackler family? A. I do not know if it was annually, I do 8 not know if it was -- what the frequency was, 8 A. No, I have not, sir. 9 9 but I remember it because we were all going in Q. You've never had a meal with a Sackler 10 to hear presentations on various wonderful 10 family member? 11 things about the company, and the clinical 11 MR. SNAPP: Object to the form. 12 12 department had to talk about the projects that A. I had -- yes, I did. I had -- when I 13 13 we had in progress, and I sat down in what was new to the company, part of introducing 14 14 looked like a perfectly wonderful set of empty somebody new to the company was that you had 15 15 seats only to be shooed out of there because lunch with the Sacklers and I had lunch with the 16 that was reserved for the family. 16 Sacklers. 17 17 Q. And do you remember the time frame? BY MR. STEWART: 18 18 Is this a single meeting that you remember, or Q. And how did that happen? Did that 19 19 were there multiple meetings like this? happen in the corporate headquarters? 20 20 A. I know of at least two. A. Yes. 21 21 Q. And were they similar meetings, the Q. And who was present? 22 22 two meetings that you described? A. Sacklers. 23 23 A. They were similar meetings. They were Q. Was Richard Sackler present? 24 progress meetings. 24 A. I'm not sure which of the Sacklers 25 Q. And where would such progress meetings 25 were present. Page 303 Page 305 Q. Do you think Kathy Sackler was 1 be held? 1 2 2 present? A. It's been too long. I don't remember. 3 They were external. We went someplace else, but 3 MR. SNAPP: Object to the form. 4 where exactly I don't remember. A. I don't know if Kathy was present. I 5 Q. Put it this way. Was it in mean, at the time I was so overwhelmed and 6 Connecticut? tired, I just said hello and good-bye, was 7 A. Yes. polite, and that was my introduction to the 8 Q. You didn't fly somewhere? 8 Sacklers. 9 9 A. No, it was in Connecticut. BY MR. STEWART: 10 Q. So you'd go off campus? 10 Q. And was that -- how many people do you 11 A. Rent a big hotel or a big hotel 11 remember were in that lunch? 12 12 conference room, an auditorium large enough to A. Five or six. 13 13 hold all the people, and then we would present. Q. And was that held in a particular 14 Q. And how many people would be present 14 dining room that you had? 15 15 at these meetings that you're describing? A. There was a dining room that -- there 16 16 was a Sackler family dining room in the old A. A bunch of employees. I mean, but I'm 17 17 not good enough at crowd estimation to guess. building. 18 18 Q. Are you talking 20 or 50? Q. And was that the only time you ever 19 19 MR. SNAPP: Object to the form. ate in the Sackler family dining room? 20 20 A. 200. A. It was, sir. 21 BY MR. STEWART: 21 Q. Other than that, have you ever had a 22 22 meal with a Sackler family member? Q. And other than those meetings -- do 23 A. I don't think so. I can't remember 23 you remember what those meetings were called? 24 A. No, I do not, sir. 24 anv. 25 25 Q. Other than those meetings that you've Q. Did you ever exchange communications

	Page 306		Page 308
1	with Richard Sackler about anything not related	1	(Whereupon, Purdue-Wright-48 was
2	to work at Purdue?	2	marked for identification.)
3	A. I don't think so.	3	(Witness reviewing document.)
4	Q. While you were at Purdue, did you ever	4	BY MR. STEWART:
5	receive anything of value from an entity other	5	Q. Do you recognize this document?
6	than Purdue itself for work you were doing with	6	A. I remember the issue. I don't
7	respect to opioids?	7	recognize the specific e-mail.
8	MR. SNAPP: Object to the form.	8	Q. So this is Dr. Sackler e-mailing you
9	A. I don't think so.	9	about the
10	BY MR. STEWART:	10	A. Yes.
11	Q. By the way, you talked about those	11	Q. And what was the basic what was he
12	presentations where there were, you know, a	12	inquiring about, as you recall?
13	couple hundred employees. Did you yourself	13	A. If I'm right, because this was a long
14	present at those meetings?	14	time ago, Algos Pain Therapeutics, or one of the
15	A. I don't think I ever did.	15	other, was one of the companies that was
16	Q. Has a member of the Sackler family	16	presenting a new product acquisition to the
17	ever given you anything of value?	17	committee, and it looks like Richard Sackler
18	MR. SNAPP: Object to the form.	18	wanted to know what I thought about it.
19	A. When I reached retirement age the	19	Q. Is that pretty commonplace for him to
20	company gave me a cuckoo clock, a clock.	20	reach out to you and try to get your thoughts on
21	BY MR. STEWART:	21	drug development and those sorts of subjects?
22	Q. Is that the extent of the list of	22	MR. SNAPP: Object to the form.
23	things of value?	23	A. I didn't even know that he'd done it
24	A. Yes, sir.	24	once. I mean, it was not a not regular in
25	Q. I hand you Exhibit 47.	25	any way.
	Page 307		Page 309
1	(Whereupon, Purdue-Wright-47 was	1	(Whereupon, Purdue-Wright-49 was
2	marked for identification.)	2	marked for identification.)
3	BY MR. STEWART:	3	BY MR. STEWART:
4	Q. Do you recognize this document?	4	Q. Let me hand you Exhibit 49. In your
5	(Witness reviewing document.)	5	dealings with Dr. Sackler, did you feel, and in
6		-	dealings with Dr. Sackier, and you reer, and in
	A. It looks like an e-mail I got, I was	6	his dealings with you, that he was a person who
7	A. It looks like an e-mail I got, I was carbon copied on.		·
7 8	•	6	his dealings with you, that he was a person who
	carbon copied on.	6 7	his dealings with you, that he was a person who spoke with precision?
8	carbon copied on.  Q. Do you know why you're copied on this,	6 7 8	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?
8	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler	6 7 8 9	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to
8 9 10	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?	6 7 8 9	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.
8 9 10 11	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.	6 7 8 9 10 11	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to
8 9 10 11 12	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a	6 7 8 9 10 11	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.
8 9 10 11 12 13	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.	6 7 8 9 10 11 12 13	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive,
8 9 10 11 12 13 14	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:	6 7 8 9 10 11 12 13	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is
8 9 10 11 12 13 14	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?	6 7 8 9 10 11 12 13 14 15	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive,
8 9 10 11 12 13 14 15	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?  A. During a period of time, and I don't	6 7 8 9 10 11 12 13 14 15	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive, did he generally speak with precision when he
8 9 10 11 12 13 14 15 16	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?  A. During a period of time, and I don't remember how long, I sat on the external product	6 7 8 9 10 11 12 13 14 15 16	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive, did he generally speak with precision when he was dealing with you?
8 9 10 11 12 13 14 15 16 17	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?  A. During a period of time, and I don't remember how long, I sat on the external product acquisition board that did scientific assessment	6 7 8 9 10 11 12 13 14 15 16 17	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive, did he generally speak with precision when he was dealing with you?  MR. SNAPP: Object to the form.
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8 9 10 11 12 13 14 15 16 17 18 19 20	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?  A. During a period of time, and I don't remember how long, I sat on the external product acquisition board that did scientific assessment of new product opportunities that were being peddled with Purdue.	6 7 8 9 10 11 12 13 14 15 16 17 18 19	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive, did he generally speak with precision when he was dealing with you?  MR. SNAPP: Object to the form.  A. I don't know what I couldn't characterize. It was so infrequent I couldn't
8 9 10 11 12 13 14 15 16 17 18 19 20 21	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?  A. During a period of time, and I don't remember how long, I sat on the external product acquisition board that did scientific assessment of new product opportunities that were being peddled with Purdue.  Q. You think that's why you would have	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive, did he generally speak with precision when he was dealing with you?  MR. SNAPP: Object to the form.  A. I don't know what I couldn't characterize. It was so infrequent I couldn't characterize how he spoke.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?  A. During a period of time, and I don't remember how long, I sat on the external product acquisition board that did scientific assessment of new product opportunities that were being peddled with Purdue.  Q. You think that's why you would have been included in this?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive, did he generally speak with precision when he was dealing with you?  MR. SNAPP: Object to the form.  A. I don't know what I couldn't characterize. It was so infrequent I couldn't characterize how he spoke.  BY MR. STEWART:
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	carbon copied on.  Q. Do you know why you're copied on this, this sequence of e-mails from Richard Sackler and others?  MR. SNAPP: Object to the form.  A. I don't know for sure, but I have a hypothesis.  BY MR. STEWART:  Q. What's that?  A. During a period of time, and I don't remember how long, I sat on the external product acquisition board that did scientific assessment of new product opportunities that were being peddled with Purdue.  Q. You think that's why you would have been included in this?  A. Most likely.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	his dealings with you, that he was a person who spoke with precision?  MR. SNAPP: Is that a question?  MR. STEWART: Yes, that's a question.  MR. SNAPP: Object to the form.  A. Sorry, I'm still orienting myself to what this is. Oh, yeah.  BY MR. STEWART:  Q. I had a general question, is  Dr. Sackler, he's a doctor, he's an executive, did he generally speak with precision when he was dealing with you?  MR. SNAPP: Object to the form.  A. I don't know what I couldn't characterize. It was so infrequent I couldn't characterize how he spoke.  BY MR. STEWART:  Q. How many times do you think you spoke

Page 310 1 Q. Did Dr. Sackler tell you anything that 1 MR. STEWART: He had 50. It's 51. 2 was inaccurate? Maybe that's another way to 2 BY MR. STEWART: 3 3 phrase that. Q. Do you recognize what this document is 4 MR. SNAPP: Object to the form. 4 about? 5 A. Not that I know of. 5 A. I'm trying to determine that. This 6 BY MR. STEWART: 6 looks like another new products evaluation 7 7 e-mail chain document. Q. Now, turning to this exhibit that is 8 8 Exhibit 49, do you have that in front of you? Q. We've seen a number of e-mails in 9 9 A. Mm-hmm. which you are included in the materials being 10 10 Q. And if you're looking at the exhibit, sent around, Dr. Sackler is included. And can 11 do you know what it is? What's this 11 we characterize most of these e-mails as e-mails 12 12 communication? in which you, he, and other top executives are 13 13 talking about new products? A. Well, I think I know what it is. One 14 14 of the intellectual property ideas that I MR. SNAPP: Object to the form. 15 15 presented to the intellectual property committee A. Thank you for the courtesy, but I was 16 was for individualized automated pharmaceutical 16 not a top executive with Purdue. I was simply 17 17 dispensing, compounding and dispensing for on the new product committee because I'd done 18 18 compounding pharmacies. Many factories have too many inventions, and so I would get a copy 19 19 high volume pharmacy so that you could program of the stuff, and I would review it, and I would 20 20 the machine, instead of a pharmacist, to go to the meeting, and then they would send --21 21 compound a specific product at a specific it looks like they were sending me copies of all 22 strength for a specific person. 22 their opinions about it. 23 23 Q. And I notice Dr. Sackler's been BY MR. STEWART: 24 wrapped into this discussion here, is that fair? 24 Q. Is it fair to say that with respect to 25 MR. SNAPP: Object to the form. 25 your company, Dr. Robert Kaiko, Michael Page 313 Page 311 1 A. It looked like it was taken away -- I Friedman, David Haddox, these were all high 2 2 was taken out of it, and it was elevated to level executives in Purdue, fair? 3 3 MR. SNAPP: Object to the form. Dr. Sackler. 4 4 A. I would characterize Paul Goldenheim, BY MR. STEWART: 5 Q. I hand you another document which I've Dr. Richard, Bob Kaiko, Michael Friedman, and I 6 marked as Exhibit 50. Do you see that? would characterize Dr. Haddox as a high level 7 (Whereupon, Purdue-Wright-50 was 7 executive by the end of his stay. 8 marked for identification.) 8 BY MR. STEWART: 9 9 BY MR. STEWART: Q. I'm going to hand you another exhibit 10 Q. Do you see what that document is? 10 marked Exhibit 52. 11 (Witness reviewing document.) 11 (Whereupon, Purdue-Wright-52 was 12 12 A. It looks like the same one. marked for identification.) 13 O. Does it seem like it's the exact same 13 BY MR. STEWART: 14 document? 14 Q. Ask you if you recognize it. 15 15 A. I think so. I'm not sure. A. It looks like an adverse event report. 16 16 Q. And was this sent by Purdue Pharma to Q. Let's set that aside. 17 17 (Whereupon, Purdue-Wright-51 was you? 18 18 marked for identification.) A. It was sent to the agency, and it 19 19 BY MR. STEWART: would have come into the mailroom, and it would 20 20 Q. I hand you a document marked 51, ask have gone to the consumer safety officer in 21 you if you recognize that document. 21 charge, and if she wanted me to read it she 22 (Witness reviewing document.) 22 would have given to me to read it, if she wanted MR. BENNER: Is this 50 or 51? 23 23 me to give it to one of the other OxyContin 24 MR. STEWART: 51. 24 reviewers she would have given it to them. 25 25 MR. BENNER: Did you skip 50? Q. Let me ask you, though, is it

H1	Ignly Confidential - Subject to	O F	
	Page 314		Page 316
1	addressed directly to you, Curtis Wright, MD?	1	primary shareholder in Adolor at the time you
2	A. Yes.	2	went there?
3	Q. And so you were still at the FDA on	3	A. I didn't know who was the primary
4	March 25th, 1997?	4	shareholder in Adolor.
5	A. Yes.	5	Q. Who did you think was providing the
6	Q. Still processing materials from	6	money that went into your paycheck when you were
7	Purdue?	7	at Adolor?
8	A. Yes.	8	A. I didn't really know.
9	Q. Now, I hand you an Exhibit 53.	9	Q. Was Adolor in any way affiliated
10	(Whereupon, Purdue-Wright-53 was	10	Purdue Pharma?
11	marked for identification.)	11	A. Not that I know of.
12	BY MR. STEWART:	12	Q. Was Adolor affiliated in any way with
13	Q. Ask you if you recognize it.	13	any member of the Sackler family?
14	(Witness reviewing document.)	14	A. Not that I knew of.
15	Q. If you'd look on the back page which	15	Q. Can you name any other person who
16	is marked by the Bates number 2207, do you see	16	owned Adolor stock other than you?
17	there is a blurb about your leaving the FDA?	17	A. Well, the president and business
18	A. Yes, I do.	18	owner, the laboratory the chief scientist
19	Q. And it says you're going to work at	19	whose name I've forgotten, too, we all got it.
20	Adolor in Malvern, Pennsylvania?	20	We had stock options, and we had the ability to
21	A. Yes.	21	purchase stock at the option price, and I bought
22	Q. Tell me, who owned Adolor?	22	all of mine.
23	A. Adolor was a venture capital	23	Q. Did they cash you out when you left?
24	pharmaceutical venture, so I don't know if it	24	A. I had to cash out when I left.
25	was owned by anybody.	25	Q. Did you ever talk to anyone at Purdue
	Page 315		Page 317
1	Q. Did you get stock when you went there?	1	about Adolor before you went to Adolor?
2	A. I got stock when I went there.	2	A. No, I don't think so.
3	Q. So you were an owner, weren't you?	3	Q. Did you, when you were still at the
4	A. I was an owner. I was a part owner.	4	FDA, call Purdue and talk about going over to
5	Q. And who was the most senior person at	5	Purdue for a job?
6	Adolor that you were ever aware of?	6	A. When I was still at the FDA?
7	A. I've forgotten his name. He was my	7	Q. Yes.
8	boss. I forgot his name.	8	A. Absolutely not.
9	Q. He recruited you?	9	Q. I think strike that.
10	A. He recruited me. He was my boss.	10	I ask you, it seems you're going from
11	I've forgotten his name.	11	the FDA to a seven person company, can you tell
12	Q. Was that the president of Adolor?	12	me why you didn't figure out who the owners of
13	A. Yes.	13	the company were before you went there?
14	Q. And how many employees were there at	14	MR. SNAPP: Object to the form.
15	Adolor when you worked there?	15	MR. PETRILLO: Objection.
16	A. I have to count. I would say seven or	16	A. It was my first job in private
17	eight.	17	industry, and I was naive and inexperienced.
18	Q. Where did Adolor get its funding?	18	BY MR. STEWART:
19	A. I'm unclear what you mean.	19	Q. Can you look on that announcement in
20	Q. Well, were you paid a salary when you	20	the e-mail chain and figure out what the date
21	were at Adolor?	21	was that you went to Adolor?
22	A. I was paid a small salary when I was	22	A. September 29th.
23	at Adolor. I was mostly given stock.	23	Q. Now, do you see in this e-mail chain
24	Q. And what who did you if you were	24	that Dr. Richard Sackler referred to your going
25	given stock, who did you understand was the	25	to Adolor as bad news?

	giry confraencial - Subject to		<u> </u>
	Page 318		Page 320
1	A. Yes.	1	Robert Reder at Purdue less than ten days after
2	Q. Did he ever talk to you about that,	2	you've left the Food and Drug Administration?
3	why he thought it was bad news that you were	3	A. Probably.
4	going to Adolor?	4	MR. PETRILLO: Objection to form.
5	A. No, but I'm not surprised.	5	BY MR. STEWART:
6	Q. Why are you not surprised?	6	Q. How while you were at Adolor, what
7	A. I was viewed as a particularly fair	7	did you what was your interaction with
8	and effective FDA reviewer.	8	Purdue?
9	Q. Including by Richard Sackler, for	9	A. I don't think we I don't think we
10	example?	10	had any interaction. I don't think they bid on
11	MR. SNAPP: Object to the form.	11	any of our portfolio.
12	A. I would assume so.	12	Q. So you would have reached out to them,
13	BY MR. STEWART:	13	though, on other occasions?
14	Q. I'm going to hand you copies.	14	MR. SNAPP: Object to the form.
15	(Whereupon, Purdue-Wright-54 was	15	A. I would have reached we were
16	marked for identification.)	16	reaching out to everybody to give the pitch.
17	BY MR. STEWART:	17	BY MR. STEWART:
18	Q. Now, do you see that this is an e-mail	18	Q. I'm going to hand you a document
19	exchange from, it looks like, Bob Reder to a	19	marked Exhibit 55.
20	series of people at Purdue?	20	(Whereupon, Purdue-Wright-55 was
21	A. It looks like an e-mail from Reder	21	marked for identification.)
22	to it looks like the usual suspects. I mean,	22	A. Mm-hmm.
23	it looks like the usual senior executives who	23	BY MR. STEWART:
24	might be involved in new product.	24	Q. And I'll just tell you, I don't think
25	Q. And do you see that he says that he	25	you've seen this exhibit, it is an excerpt from
			P 221
1	Page 319	1	Page 321
1	received a telephone call I'll just quote it.	1	a deposition of Richard Sackler. Could you turn
2	received a telephone call I'll just quote it. "I received a telephone call today from	2	a deposition of Richard Sackler. Could you turn to Page 112, which is the second page in the
2 3	received a telephone call I'll just quote it. "I received a telephone call today from Dr. Curtis Wright, who was formerly of the FDA	2 3	a deposition of Richard Sackler. Could you turn to Page 112, which is the second page in the exhibit which is Exhibit 55?
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2 3 4 5 6	received a telephone call I'll just quote it. "I received a telephone call today from Dr. Curtis Wright, who was formerly of the FDA ODE3 and is now Vice President of Research for Adolor." He gives the address. Do you see that?	2 3 4 5 6	a deposition of Richard Sackler. Could you turn to Page 112, which is the second page in the exhibit which is Exhibit 55?  A. Mm-hmm.  Q. And do you see that there's a question is asked, okay, about Curtis Wright, and the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	received a telephone call I'll just quote it.  "I received a telephone call today from Dr. Curtis Wright, who was formerly of the FDA ODE3 and is now Vice President of Research for Adolor." He gives the address.  Do you see that?  A. Mm-hmm. Q. Did I read that correctly? A. You read that correctly. Q. So he's saying that you called him. Do you remember making that phone call? A. I don't remember making that phone call, but I have no reason to believe not. Q. If Robert Reder said you made a phone call, he's a credible guy A. Yes. Q and that makes sense? And you were reaching out to discuss the possibility of cooperation between Adolor and Purdue on a product? A. Peddling our wares. Q. Okay. Do you see that the date of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	a deposition of Richard Sackler. Could you turn to Page 112, which is the second page in the exhibit which is Exhibit 55?  A. Mm-hmm.  Q. And do you see that there's a question is asked, okay, about Curtis Wright, and the question is asked, "And at that time he was the person who was reviewing your-all's OxyContin submission to the FDA?"  Do you see that?  A. Mm-hmm.  Q. Do you see that Richard Sackler's answer is "He was the medical reviewer, that's correct."  Do you see that?  A. Mm-hmm.  Q. And that's accurate, you were the medical reviewer for the OxyContin?  A. I was one of the medical reviewers.  Q. So you were a medical reviewer for OxyContin, fair? Mr. Sackler's description is correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	received a telephone call I'll just quote it.  "I received a telephone call today from Dr. Curtis Wright, who was formerly of the FDA ODE3 and is now Vice President of Research for Adolor." He gives the address.  Do you see that?  A. Mm-hmm. Q. Did I read that correctly? A. You read that correctly. Q. So he's saying that you called him. Do you remember making that phone call? A. I don't remember making that phone call, but I have no reason to believe not. Q. If Robert Reder said you made a phone call, he's a credible guy A. Yes. Q and that makes sense? And you were reaching out to discuss the possibility of cooperation between Adolor and Purdue on a product? A. Peddling our wares. Q. Okay. Do you see that the date of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	a deposition of Richard Sackler. Could you turn to Page 112, which is the second page in the exhibit which is Exhibit 55?  A. Mm-hmm.  Q. And do you see that there's a question is asked, okay, about Curtis Wright, and the question is asked, "And at that time he was the person who was reviewing your-all's OxyContin submission to the FDA?"  Do you see that?  A. Mm-hmm.  Q. Do you see that Richard Sackler's answer is "He was the medical reviewer, that's correct."  Do you see that?  A. Mm-hmm.  Q. And that's accurate, you were the medical reviewer for the OxyContin?  A. I was one of the medical reviewers.  Q. So you were a medical reviewer for OxyContin, fair? Mr. Sackler's description is correct?

Page 322 Page 324 1 you know, allowed you-all to" take it -- "sell 1 MR. SNAPP: Object to the form. 2 it from the FDA?" And Richard Sackler says 2 A. I didn't say that. I hadn't -- I 3 3 "That's my recollection." wasn't monitoring my boss for the accuracy of 4 4 Do you see that? his comments. 5 MR. PETRILLO: I think you misread it, BY MR. STEWART: 6 but pretty close. Q. I guess I'm saying, all the other 7 7 BY MR. STEWART: times, you can't remember him making another 8 Q. Why don't I read it again. Strike 8 inaccurate statement, can you, in your dealings 9 9 that. Here's what I'm reading. with him at Purdue? 10 10 "Question: And he's the guy" --MR. SNAPP: Object to the form. 11 parenthetically referring to you -- "that 11 A. I didn't have enough dealings with him 12 12 actually approved it to be sold, you know, to know. 13 allowed you-all to sell it from the FDA?" 13 BY MR. STEWART: 14 14 Do you see that question? Q. Well, in the limited dealings you had, 15 15 A. I see that question. and we went through a series of e-mails, he 16 16 Q. And Dr. Sackler says "That's my never made a statement to you that was 17 17 recollection." inaccurate, fair? 18 18 Do you see that? A. That's true. 19 19 A. Mm-hmm. Q. But you're saying in this case when he 20 20 Q. Now, the next question is -- and by says that you called Purdue when you were 21 the way, Dr. Sackler's recollection is accurate, 21 planning on leaving the FDA, you think that is 22 22 is that fair? an inaccurate statement? 23 23 A. So far. A. That is inaccurate. 24 Q. Do you see the next question is 24 Q. And we would just have to get 25 "You-all ultimately hired him a few years later, Dr. Sackler on the stand and figure out how to Page 323 Page 325 didn't you?" And Dr. Sackler's answer is, "We untangle this inaccuracy, fair? 1 1 2 2 MR. PETRILLO: Objection. did hire him, but not after his tenure at the 3 FDA. We -- he spoke to somebody at Purdue when 3 MR. SNAPP: Object to the form. 4 he was planning on leaving the FDA, and Paul and 4 BY MR. STEWART: 5 I discussed it and agreed that we should not 5 Q. Is that correct? 6 hire somebody who had -- who had reviewed our 6 A. I don't know what you would have to 7 7 product and had left. And so he went to another do. I don't know why you would want to do it. 8 company, regrettably for us, because he was But I can assure you I was recruited by the 9 9 very, very knowledgeable." president of Adolor out of the agency, and I, up 10 Do you see that? 10 to the point where he started talking to me, I 11 11 had not really had plans to leave the agency. A. Yes. 12 12 Q. Now, do you see that Dr. Sackler's Q. Did you ever ask the president of 13 testifying that you did contact Purdue while you 13 Adolor "who owns this company?" 14 were at the FDA. 14 A. No. 15 15 Do you see that? MR. STEWART: Let's take a break and 16 16 A. Yes. then we'll come back and finish up. 17 17 MR. SNAPP: Object to the form. THE VIDEOGRAPHER: We are now going 18 BY MR. STEWART: 18 off the record, and the time is 6:35 p.m. 19 19 Q. Can you explain that? (Whereupon, a recess was taken.) 20 MR. SNAPP: Object to the form. 20 THE VIDEOGRAPHER: We are now going 21 A. He's wrong. He's just wrong. 21 back on the record, and the time is 6:42 p.m. 22 MR. STEWART: Dr. Wright, I'm told 22 BY MR. STEWART: 23 we're effectively out of time, so thank you. 23 Q. So in your dealings with Dr. Sackler, 24 this is the first instance you can recall when 24 And I'm going to keep the deposition open, but 25 25 he's made an inaccurate statement, in your view? of course, subject to the agreement that I

Page 326 1 announced with counsel earlier, and that's --1 MS. SINGER: Okay. One question. Off 2 I'm done with my questions today. 2 the record. 3 3 MR. SNAPP: I have no questions. THE VIDEOGRAPHER: Okay. Conclude? 4 4 MS. SINGER: I have just a few. I MS. SINGER: Conclude. 5 5 can't. Never mind. There was one document that THE VIDEOGRAPHER: We are now going 6 we needed to just clear up because we gave you 6 off the record, and the time is 6:48 p.m. 7 7 all pieces of it. (Whereupon, the deposition was 8 8 MR. PETRILLO: Do you want to put that concluded.) 9 9 on the record, do you have a clean one? 10 10 MR. SNAPP: Do you want to just 11 substitute in a clean one? 11 12 12 MS. SINGER: Yeah, I mean, I'd love to 13 13 be able to ask the one question about the page 14 14 we didn't have, but I'm at your mercy on that. 15 15 MR. SNAPP: Can we go off the record? 16 THE VIDEOGRAPHER: We are now going 16 17 17 off the record, and the time is 6:43 p.m. 18 18 (Whereupon, a recess was taken.) 19 THE VIDEOGRAPHER: We are now going 19 20 20 back on the record, and the time is 6:46 a.m. 21 21 **FURTHER EXAMINATION** 22 22 BY MS. SINGER: 23 23 Q. All right. Dr. Wright, I'm reshowing 24 you Exhibit 31, we had a missing pages issue 24 25 25 earlier in your deposition, so could you take a Page 327 Page 329 look and confirm that this is an Integrated 1 CERTIFICATE 1 2 2 Summary of Safety that you saw earlier with all 3 3 of the pages there? I, MAUREEN O'CONNOR POLLARD, LSR #473, 4 4 RMR, CLR, and Notary Public, do hereby certify (Witness reviewing document.) that there came before me on the 19th day of 5 A. Yeah, it is. 6 Q. And I want to direct your attention to December, 2018, the person hereinbefore named, 7 who was duly sworn to testify to the truth of Bates number 040. In the interest of time I 8 will read you the section under "ADE their knowledge concerning the matters in this 9 9 Conclusion." "The trial data set does not cause, and their examination reduced to 10 support a definite conclusion that the CR form 10 typewriting under my direction and is a true 11 11 record of the testimony. has fewer adverse events than the IR form in the 12 12 intended population of use. There is a thin but 13 13 possible trend toward a lower frequency of I further certify that I am neither 14 opioid adverse effects for CR in patients not 14 attorney for or related or employed by any of 15 15 tolerant of opioids suggested by the PK data in the parties to the action, and that I am not a 16 16 relative or employee of any attorney or counsel normal volunteers." 17 17 employed by the parties hereto or financially Have I read that accurately? 18 18 interested in the action. A. You have read that accurately. 19 19 Q. And does that refresh your In witness whereof, I have hereunto 20 recollection as to when OxyContin had a better 20 set my hand and seal this 24th day of December, 21 21 safety profile than other opioids, than IR 22 22 opioids? 23 MAUREEN O'CONNOR POLLARD, License #473 23 MR. SNAPP: Object to the form. 24 A. I would characterize that as a hint, 24 Realtime Systems Administrator, RMR 25 Notary Commission Expires: 10/31/2022 25 but not proof.

	Page 330		Page 332
1	INSTRUCTIONS TO WITNESS	1	ACKNOWLEDGMENT OF DEPONENT
2		2	
3	Please read your deposition over	3	
4	· -	4	I do
	carefully and make any necessary corrections.		I,, do
5	You should state the reason in the appropriate	5	Hereby certify that I have read the foregoing
6	space on the errata sheet for any corrections	6	pages, and that the same is a correct
7	that are made.	7	transcription of the answers given by me to the
8	After doing so, please sign the	8	questions therein propounded, except for the
9	errata sheet and date it. It will be attached	9	corrections or changes in form or substance, if
10	to your deposition.	10	any, noted in the attached Errata Sheet.
11	It is imperative that you return	11	any, noted in the attached Effata sheet.
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	the original errata sheet to the deposing		WIEDLEGG NAME DAME
13	attorney within thirty (30) days of receipt of	13	WITNESS NAME DATE
14	the deposition transcript by you. If you fail	14	
15	to do so, the deposition transcript may be	15	
16	deemed to be accurate and may be used in court.	16	
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18		18	Subscribed and sworn
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